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

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2019

OR

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

For the transition period from _____ to _____

Commission file number: 001-36278

Adynxx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**58-2349413**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
100 Pine Street, Suite 500 **San Francisco, CA**	**94111**
(Address of principal executive offices)	**(Zip Code)**

(415) 512-7740
(Registrant's telephone number, including area code)

Alliqua BioMedical, Inc.
2150 Cabot Blvd West, Suite B
Langhorne, PA
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	ADYX (OTCQB)	N/A

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

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

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

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 Act). Yes ☐ No ☒

As of November 10, 2019 the registrant had 5,807,877 shares of Common Stock, $0.001 par value per share, outstanding.

ADYNXX, INC. (FORMERLY ALLIQUA BIOMEDICAL, INC.)
FORM 10-Q
FOR THE QUARTER ENDEDSEPTEMBER 30, 2019

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Where You Can Find More Information

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (ir.adynxx.com), SEC filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with our stockholders and the public about our company, our product candidates and other matters. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2019 (unaudited)	December 31, 2018
Assets:		
Current assets		
Cash and cash equivalents	$ 331	$ 1,887
Restricted cash	253	55
Prepaid expenses and other current assets	1,960	10
Total current assets	2,544	1,952
Property and equipment, net	5	10
Right of use asset, net	687	-
Other assets	18	18
Total assets	$ 3,254	$ 1,980
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit:		
Current liabilities		
Accounts payable	$ 2,659	$ 491
Accrued liabilities	2,173	857
Current portion of operating lease liability	224	-
Convertible promissory notes - related party	6,348	4,500
Term loan, net of discount	2,393	3,812
Total current liabilities	13,797	9,660
Operating lease liability, net of current portion	519	-
Warrant liability	-	140
Commitments and contingencies (Note 12)		
Redeemable convertible preferred stock		
Series A redeemable convertible preferred stock, $0.001 par value; 0 shares authorized, issued and outstanding at September 30, 2019 (unaudited); 2,046,378 shares authorized, 2,034,548 shares issued and outstanding at December 31, 2018	-	12,814
Series B redeemable convertible preferred stock, $0.001 par value; 0 shares authorized, issued and outstanding at September 30, 2019 (unaudited); 1,833,387 shares authorized, issued and outstanding at December 31, 2018	-	15,897
Stockholders' deficit		
Preferred stock, $0.001 par value; 1,000,000 shares authorized no shares issued or outstanding	-	-
Common stock, $0.001 par value; 95,000,000 shares authorized, 5,807,877 shares issued and outstanding at September 30, 2019 (unaudited) 5,313,200 shares authorized, 701,808 shares issued and outstanding at December 31, 2018	6	1
Additional paid-in capital	35,244	747
Accumulated deficit	(46,312)	(37,279)
Total stockholders' deficit	(11,062)	(36,531)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 3,254	$ 1,980

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

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Statements of Operations

(In thousands, except share and per share data) (Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 1,986	$ 524	$ 5,212	$ 1,793
General and administrative	1,037	810	3,354	2,102
Grant reimbursements	(716)	-	(1,914)	-
Gain on settlement	(635)	-	(635)	-
Total operating expenses, net	1,672	1,334	6,017	3,895
Loss from operations	(1,672)	(1,334)	(6,017)	(3,895)
Interest expense, net	(223)	(322)	(2,864)	(767)
Other income (expense), net	-	151	(94)	211
Loss from continuing operations	(1,895)	(1,505)	(8,975)	(4,451)
Loss from discontinued operations	-	-	(58)	-
Net loss	$ (1,895)	$ (1,505)	$ (9,033)	$ (4,451)
Net loss per basic and diluted share:				
Loss from continuing operations	$ (0.33)	$ (2.14)	$ (2.56)	$ (6.34)
Loss from discontinued operations	-	-	(0.02)	-
Net loss per basic and diluted share	$ (0.33)	$ (2.14)	$ (2.58)	$ (6.34)
Weighted-average number of common shares outstanding - basic and diluted	5,807,877	701,808	3,507,338	701,808

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

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit

(In thousands, except share amounts) (Unaudited)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2018	2,034,548	$ 12,814	1,833,387	$ 15,897	701,808	$ 1	$ 747	$ (37,279)	$ (36,531)
Stock-based compensation expense	-	-	-	-	-	-	84	-	84
Net loss	-	-	-	-	-	-	-	(2,462)	(2,462)
Balance, March 31, 2019	2,034,548	$ 12,814	1,833,387	$ 15,897	701,808	$ 1	$ 831	$ (39,741)	$ (38,909)
Conversion of convertible notes and accrued interest into convertible preferred stock	-	-	367,041	3,203	-	-	-	-	-
Recognition of beneficial conversion feature upon conversion of convertible notes	-	-	-	2,101	-	-	-	-	-
Conversion of convertible preferred stock into common stock	(2,034,548)	(12,814)	(2,200,428)	(21,201)	4,234,976	4	34,011	-	34,015
Issuance of common stock for merger	-	-	-	-	854,017	1	5,246	-	5,247
Equity issuance costs paid in stock	-	-	-	-	17,076	-	-	-	-
Exchange of warrants	-	-	-	-	-	-	234		234
Dividend	-	-	-	-	-	-	(5,245)	-	(5,245)
Spin-off of AquaMed	-	-	-	-	-	-	(1)	-	(1)
Stock-based compensation expense	-	-	-	-	-	-	84	-	84
Net loss	-	-	-	-	-	-	-	(4,676)	(4,676)
Balance, June 30, 2019	-	$ -	-	$ -	5,807,877	$ 6	$ 35,160	$ (44,417)	$ (9,251)
Stock-based compensation expense	-	-	-	-	-	-	84	-	84
Net loss	-	-	-	-	-	-	-	(1,895)	(1,895)
Balance, September 30, 2019	-	$ -	-	$ -	5,807,877	$ 6	$ 35,244	$ (46,312)	$ (11,062)
Balance, December 31, 2017	2,034,548	$ 12,814	1,833,387	$ 15,897	701,808	$ 1	$ 438	$ (31,294)	$ (30,855)
Stock-based compensation expense	-	-	-	-	-	-	75	-	75
Net loss	-	-	-	-	-	-	-	(1,523)	(1,523)
Balance, March 31, 2018	2,034,548	12,814	1,833,387	15,897	701,808	1	513	(32,817)	(32,303)
Stock-based compensation expense	-	-	-	-	-	-	75	-	75
Net loss	-	-	-	-	-	-	-	(1,422)	(1,422)
Balance, June 30, 2018	2,034,548	12,814	1,833,387	15,897	701,808	1	588	(34,239)	(33,650)
Stock-based compensation expense	-	-	-	-	-	-	75	-	75
Net loss	-	-	-	-	-	-	-	(1,505)	(1,505)
Balance, September 30, 2018	2,034,548	$ 12,814	1,833,387	$ 15,897	701,808	$ 1	$ 663	$ (35,744)	$ (35,080)

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

Adynxx, Inc. (formerly Alliqua Biomedical, Inc.)
Condensed Consolidated Statements of Cash Flows

(In thousands) (Unaudited)

	Nine months ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (9,033)	$ (4,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5	6
Stock-based compensation expense	252	225
Changes in fair value of warrant liability	94	-
Changes in fair value of derivative liability	-	(211)
Accretion of final charge upon maturity of Oxford Term Loan A and B	187	161
Amortization of issuance cost and discounts for term loans and convertible notes	20	258
Non-cash interest expense on convertible promissory notes	2,426	62
Amortization of right-of-use asset	232	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,948)	13
Other assets	57	-
Accounts payable	2,168	(570)
Accrued liabilities	1,006	(142)
Lease liability	(233)	-
Net cash used in operating activities	(4,767)	(4,649)
Cash flows from investing activities:		
Purchases of property and equipment	-	(2)
Net cash used in investing activities	-	(2)
Cash flows from financing activities:		
Payments on term loan	(1,437)	(890)
Proceeds from issuance of convertible promissory notes - related party	4,846	3,000
Net cash provided by financing activities	3,409	2,110
Net decrease in cash, cash equivalents and restricted cash	(1,358)	(2,541)
Cash, cash equivalents and restricted cash at beginning of period	1,942	4,356
Cash, cash equivalents and restricted cash at end of period	$ 584	$ 1,815
Other supplemental disclosure:		
Cash paid for interest	$ 231	$ 286
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for operating lease obligations[(1)]	$ 227	$ -
Reclassification of warrant liability to paid in capital	$ 234	$ -
Conversion of convertible preferred stock into common stock	$ 34,015	$ -
Conversion of convertible notes and accrued interest into convertible preferred stock	$ 3,203	$ -

	September 30, 2019	**September 30, 2018**
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 331	$ 1,760
Restricted cash	253	55
Cash, cash equivalents and restricted cash at end of period	$ 584	$ 1,815

(1) Amounts for the nine months ended September 30, 2019 pertains to the transition adjustment for the adoption of ASC 842.

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

Note 1. Organization and Basis of Presentation

The Company

On May 3, 2019, Adynxx, Inc. ("Adynxx" or the "Company"), formerly known as "Alliqua BioMedical, Inc." ("Alliqua") completed its reverse merger with what was then known as "Adynxx, Inc." ("Private Adynxx"), which we refer to as the Merger. This transaction was accounted for as a reverse merger and a recapitalization effected by a share exchange. See *'Note 3 – Reverse Merger'*.

The Company is a clinical stage biopharmaceutical company focused on the development of a new class of therapeutics called transcription factor decoys and bringing to market novel, disease-modifying products to address unmet needs in the treatment of pain and inflammation. The Company is primarily engaged in developing initial product technology, recruiting personnel, conducting clinical trials and raising capital.

Basis of Presentation

These unaudited financial statements represent the condensed consolidated financial statements of Adynxx and, for periods prior to the Merger, the condensed consolidated financial statements of Private Adynxx. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and pursuant to the instructions of the SEC on Form 10-Q and Article 10 of Regulation S-X of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these unaudited condensed consolidated financial statements contain all adjustments necessary to present fairly the Company's financial position on a consolidated basis and the consolidated results of operations and cash flows for the interim periods presented. The results of operations for the periods September 30, 2019 and 2018 are not necessarily indicative of expected operating results for the full year. The information presented throughout the document as of and for the periods ended September 30, 2019 and 2018 is unaudited. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements and the notes thereto as set forth in the Company's Form 8-K/A filed with the SEC on June 10, 2019.

All share and per share data for all periods presented have been retroactively restated to reflect the exchange ratio used in the Merger of 0.0359 shares of common stock in exchange for each share of Private Adynxx, Inc. common stock outstanding immediately prior to the Merger (which exchange rate reflects a 1-for-6 reverse stock split of the issued and outstanding capital stock of Alliqua BioMedical, Inc. effected on May 3, 2019 immediately prior to the Merger).

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amount of assets, liabilities, revenue, costs, expenses and other (expenses) income that are reported in the condensed consolidated financial statements and accompanying disclosures. These estimates are based on management's best knowledge of current events, historical experience, actions that the Company may undertake in the future and on various other assumptions that are believed to be reasonable under the circumstances. As a result, actual results may be different from these estimates.

Liquidity

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As of September 30, 2019, the Company had $331,000 in cash and cash equivalents, had term loans ("Term Loans"), including accrued interest outstanding, of $3.0 million from Oxford Finance, LLC ("Oxford"), and $6.6 million aggregate principal amount of convertible promissory notes ("Notes"), including accrued interest, outstanding. From inception through September 30, 2019, the Company had an accumulated deficit of approximately $46.3 million. The Company expects to incur substantial losses in future periods. The Company is subject to risks common to companies in the clinical stage, including, but not limited to, development of new products, development of markets and distribution channels, dependence on key personnel, and the ability to obtain additional capital as needed to fund its product development plans. The Company has a limited operating history and has yet to generate any revenues from customers. There is no guarantee that profitable operations, if ever achieved, could be sustained on a continuing basis.

The Company plans to finance its operations and capital funding needs through equity and/or debt financing. However, there can be no assurance that additional funding will be available to the Company on acceptable terms on a timely basis, if at all, or that the Company will generate sufficient cash from operations to adequately fund operating needs or ultimately achieve profitability. The conditions above, among others, raise substantial doubt about the ability of the Company to continue as a going concern within one year after the date of the issuance of the financial statements.

The accompanying financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of expenses incurred during the reporting period. Actual results could differ from those estimates and such differences could be material to the Company's financial position and results of operations.

Significant estimates and assumptions include the valuation of equity instruments and equity-linked instruments, including the valuation of the Company's common stock and the valuation of the Company's common stock options for purposes of accounting for stock-based compensation, and accruals for clinical trials and the valuation allowances on deferred tax assets.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Cash and cash equivalents are deposited in demand and money market accounts with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation insured limits. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company based on intellectual property, patent, product, regulatory, or other factors; and the Company's ability to attract and retain employees necessary to support its growth.

The Company's postoperative pain reduction product candidate, brivoligide, is an oligonucleotide. The Company currently uses Nitto-Denko Avecia, Inc. ("Avecia") as a single supplier for the brivoligide drug substance. There are currently a limited number of oligonucleotide manufacturers with commercial scale capabilities globally. While the Company intends to develop secondary sources for manufacturing of its drug candidates in the future, there can be no assurance that it will be able to do so on commercially reasonable terms, or at all. Any interruption in the supply of this key material could significantly delay the research and development process or increase the expenses for development and commercialization of the Company's product candidates. The quality of materials can be critical to the performance of a drug delivery technology. Therefore, the lack of a reliable source that provides a consistent supply of high quality materials would harm the Company. At September 30, 2019, this vendor represented 26% of total accounts payable.

At September 30, 2019, three vendors represented 26%, 26% and 23% of total accounts payable, respectively. One of these vendors supported clinical study activities and accounted for 26% of the total accounts payable. The second vendor supported manufacturing activities and accounted for 26% of the total accounts payable. The third vendor supported general and administrative activities associated with the Merger and the next round of equity financing. At December 31, 2018, three vendors represented 52%, 26% and 15% of total accounts payable. Two of these vendors supported general and administrative activities, primarily associated with the Merger and next round of equity financing, which accounted for 67% of the total accounts payable. The remaining vendor supported clinical study activities.

Clinical Trial Accruals

The Company's clinical trial accruals are based on patient enrollment and related costs at clinical investigator sites as well as for the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations ("CROs") that conduct and manage clinical trials on the Company's behalf. The Company accrues expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity according to the clinical trial protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, the Company modifies the estimates of accrued expenses accordingly. To date, the Company has had no significant adjustments to accrued clinical trial expenses.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less on the date of acquisition to be cash and cash equivalents.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using a straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the remaining term of the lease.

Expenditures for repairs and maintenance are charged to expense as incurred. Upon disposition of an asset, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in the statements of operations.

Impairment of Long-Lived Assets

The Company's long-lived assets and other assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds its fair value. As of September 30, 2019 and December 31, 2018, the Company had not experienced any impairment losses on its long-lived assets.

Restricted Cash

At September 30, 2019, the Company had $198,000 restricted from withdrawal and held by a bank in the form of a secured money market account as collateral for Oxford in conjunction with a debt amendment that occurred in January 2019. In addition, as of September 30, 2019 and December 31, 2018, the Company had $55,000 restricted and held by a bank as collateral for a letter of credit provided to the Company's facility landlord.

Stock-Based Compensation

Stock-based compensation is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company recognizes forfeitures as they occur.

The Company uses the Black-Scholes option-pricing model (the "Black-Scholes model") as the method for determining the estimated fair value of stock options.

Expected Term—The expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method.

Expected Volatility—Expected volatility is estimated using comparable public companies' volatility for similar terms.

Expected Dividend—The Black-Scholes model calls for a single expected dividend yield as an input. Other than the dividend paid in connection with the Merger, the Company has never paid dividends and has no plans to pay dividends.

Risk-Free Interest Rate—The risk-free interest rate used in the Black-Scholes model is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Research and Development

Research and development expenses consist of personnel costs, including salaries, benefits and stock-based compensation, preclinical studies, clinical studies performed by CROs, materials and supplies, licenses and fees, and overhead allocations consisting of various administrative and facilities related costs. The Company charges research and development costs, including clinical study costs, to expense when incurred.

Collaboration Agreement

In June 2018, the Company entered into a collaboration agreement with twoXAR, an artificial intelligence-driven drug discovery company, in order to identify potential product candidates for the treatment of endometriosis. In May 2019, the Company made a collaboration initiation payment of $75,000, which was charged to research and development expenses when incurred.

In June 2019, Adynxx received an initial set of candidate predictions from twoXAR. The Company has initiated a review of the potential products to determine if any are viable candidates for further research and development.

Grant Reimbursements

In December 2018, the Company received a Notice of Award from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health ("NIH"), to support the clinical development of its lead product candidate, brivoligide. NIH grants provide funds for certain types of expenditures in connection with research and development activities over a contractually defined period. The maximum funding expected to be available under this grant for qualified expenditures over the two-year period through December 2020 is approximately $5.7 million.

On January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2018-08, "Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made." Based on this guidance, the Company determined that grant payments received met the definition of a 'conditional contribution' (versus an exchange contract) because (i) the Company has limited discretion in the way the funds may be spent, which creates a barrier to entitlement, and (ii) the grant contains provisions that release the awarding agency from the obligation to transfer funds that are not expended at the time the award is terminated. The Company recognizes grant reimbursements as a contra operating expense and reflects this as a component of its loss from operations in the period during which the qualifying expenses are incurred and the related services rendered, provided that the applicable performance obligations have been met.

For the three and nine months ended September 30, 2019, the Company incurred qualified expenses and recognized $0.7 million and $1.9 million of grant reimbursements, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance, which would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made.

The Company recognizes the tax benefit from uncertain tax positions in accordance with GAAP, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a company's tax return.

Net Loss per Basic and Diluted Share

Net loss per basic common share is computed on the basis of the net loss for the period divided by the weighted average number of common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common shares and of common share equivalents outstanding when dilutive. Common share equivalents include outstanding stock options, warrants and non-vested restricted stock which are included under the treasury share method when dilutive. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be antidilutive.

Convertible Preferred Stock Warrants

At December 31, 2018, freestanding warrants to acquire shares of convertible preferred stock were classified as liabilities on the accompanying balance sheet. These warrants were subject to remeasurement at fair value at each balance sheet date, and any change in fair value is recognized as a component of other income or expense. In connection with the Merger, the warrants were exchanged into warrants that no longer met the definition of a derivative and thus, the balance was reclassified into equity during the three and nine months ended September 30, 2019.

Debt Modifications and Extinguishments

When the Company modifies debt, it accounts for the impact of such modification in accordance with Accounting Standards Codification ("ASC") 470-50, *Debt: Modifications and Extinguishments*, which requires modification to debt instruments to be evaluated to assess whether the modifications are considered "substantial modifications". A substantial modification of terms shall be accounted for like an extinguishment. Based on the guidance relied upon and the analysis performed, the Company determined that the October 2018 modification of the March 2018 and September 2018 Notes, to add an additional conversion option in the event of a reverse merger, was considered to be a "substantial modification". As a result, it treated this modification as an 'extinguishment' of those debts and recognized $11,000 of net gain from this debt extinguishment in other income in October 2018. All other changes to debt provisions were not considered substantial and were treated as debt modifications, with the exception of the modification in August 2019 which was accounted for as a troubled debt restructuring.

Derivative Instruments

ASC 815-15, *Derivatives and Hedging: Embedded Derivatives*, generally provides three criteria that, if met, require companies to bifurcate conversion options from their host instruments and account for them as freestanding derivative financial instruments. These three criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument subject to the requirement of ASC 815.

At September 30, 2019 and December 31, 2018, the Company maintained outstanding Notes which contained various embedded derivative features. In particular, these Notes contained the following features:

1) A share settled redemption in a qualified preferred stock financing; and

2) The right to an accelerated cash repayment in the event of a change in control.

These embedded features were not considered clearly and closely related to the debt host, therefore, they were bifurcated and accounted for separately from the debt host as a derivative liability. Derivative financial liabilities are initially recorded at fair value, with gains and losses arising from changes in fair value recognized in the statement of operations at each period end while such instruments are outstanding.

As of September 30, 2019, and December 31, 2018, the Company determined that there was no fair value associated with the embedded derivatives that remained with the outstanding convertible notes. See *'Note 7 - Term Loans and Convertible Promissory Notes'* for further discussion of the Notes and the bifurcated derivative liability.

Fair Value of Financial Instruments

ASC 820-10, *Fair Value Measurement*, provides a framework for measuring fair value under GAAP and requires expanded disclosures regarding fair value measurements. The standard defines fair value as an exit price, representing the amount that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. The standard also establishes a fair value hierarchy, which prioritizes the inputs used in measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2—Inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date.

This hierarchy requires the use of observable market data when available and to minimize the use of unobservable inputs when determining fair value.

The following table presents the Company's fair value hierarchy for its warrant liability measured at fair value on a recurring basis at December 31, 2018 (in thousands):

	As of December 31, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
Financial liabilities				
Warrant liability	$ -	$ -	$ 140	$ 140
Total financial liabilities	$ -	$ -	$ 140	$ 140

The Level 3 derivative at December 31, 2018 consisted of a warrant liability of Private Adynxx that, at December 31, 2018, was exerciseable into preferred shares that were potentially redeemable. In connection with the Merger, the warrants were exchanged into warrants that no longer met the definition of a derivative and thus, the balance was reclassified into equity in May 2019.

The change in fair value of the warrant liability for the three and nine months ended September 30, 2019 and 2018 are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Fair value, beginning of period	$ -	$ 42	$ 140	$ 42
Change in fair value of preferred stock warrants	-	1	94	1
Exchange of warrants upon Merger	-	-	(234)	-
Fair value at end of period	$ -	$ 43	$ -	$ 43

The carrying amounts reported in the accompanying balance sheets for cash and cash equivalents, accounts payable and accrued liabilities approximate their fair value due to their short maturities. The fair value of the Company's term loan is based on the borrowing rate currently available to the Company for borrowings with similar terms and maturity and approximates its carrying value.

Derivative liability instruments are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. Level 3 liability instruments consist of the preferred stock warrant liability and derivative liability, for both of which there is no observable market data for the determination of fair value and requires significant management judgment and estimation.

While the Company's Notes contain embedded derivative liabilities, the Company determined that the fair value of these liabilities were zero at September 30, 2019 and December 31, 2018. See '*Note 7 - Term Loans and Convertible Promissory Notes'* for further discussion on the derivative liability activity.

The change in fair value of the derivative liability relating to the Notes for the three and nine months ended September 30, 2019 and 2018 is summarized below (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Fair value, beginning of period	$ -	$ 436	$ -	$ -
Embedded derivative liability from the issuance of Notes	-	369	-	864
Change in value of embedded derivatives	-	(152)	-	(211)
Fair value at end of period	$ -	$ 653	$ -	$ 653

Discontinued Operations

Discontinued operations represent the activities of the AquaMed business that was assumed in connection with the Merger and subsequently spun off during the three months ended June 30, 2019. See '*Note 3 – Reverse Merger'*. There are no ongoing activities or obligations associated with discontinued operations at September 30, 2019.

Recently Adopted Accounting Pronouncements

Lease Accounting

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months on the balance sheet. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company adopted the new standard on January 1, 2019 and used the effective date as its date of initial application. Consequently, the Company has not adjusted prior period amounts.

The Company has elected the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs would have met the definition of initial direct costs in ASC Topic 842 at lease commencement.

The most significant impact from the adoption of this standard was the recognition of right-of-use ("ROU"), assets and lease obligations on the balance sheet for operating leases. This standard did not have a material impact on the Company's cash flows from operations and operating results. As a result of the adoption of the new lease accounting guidance, the Company recognized on January 1, 2019 (a) a lease liability of approximately $227,000, which represents the present value of the remaining lease payments of approximately $239,000, discounted using the Company's incremental borrowing rate of 9.41%, and (b) a right-of-use asset of approximately $227,000 which represents the lease liability of $227,000. The ROU asset is being amortized over the remaining term of the lease of twelve months from January 1, 2019.

Recent Accounting Pronouncements Not Yet Effective

In August 2018, the FASB issued No. ASU 2018-13, Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820). This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. This ASU is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year, with early adoption permitted. The Company is currently assessing whether these amendments will have a material effect on its financial statements.

Note 3. Reverse Merger

Merger

On May 3, 2019 the Company completed its reverse merger with Alliqua. Immediately following the Merger, the combined company's name was changed from "Alliqua BioMedical, Inc." to "Adynxx, Inc." Private Adynxx changed its name to "Adynxx Sub, Inc." and is currently a wholly-owned subsidiary of the Company. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Subject to the terms and conditions of the Merger Agreement (a) each outstanding share of capital stock of Private Adynxx, was converted into the right to receive the number of shares of Alliqua's common stock equal to the exchange ratio formula in the Merger Agreement ("Exchange Ratio") of 0.0359 shares of common stock (which exchange rate reflects a 1-for-6 reverse stock split of the issued and outstanding capital stock of Alliqua BioMedical, Inc. effected on May 3, 2019 immediately prior to the Merger).and (b) each outstanding Private Adynxx stock option, whether vested or unvested, and warrant that has not previously been exercised, was assumed by the post-Merger company and converted into a stock option or warrant, as the case may be, to purchase shares of the post-Merger Company's common stock at the Exchange Ratio formula in the Merger Agreement.

On May 3, 2019, prior to the closing of the Merger, $3.0 million aggregate principal amount of Notes and $203,000 of cumulative accrued interest on such Notes were converted into 367,041 shares of preferred stock, which were converted into common stock upon completion of the merger.

Upon the completion of the Merger, Private Adynxx equity holders held 4,936,784 shares of common stock. Equity issuance costs in connection with the Merger were recorded as an offset to additional paid in capital.

As described in "Spin-off" below, at the time of the Merger, Alliqua had in place a plan to spin-off all existing operations. Since Alliqua was deemed to have no operations upon consummation of the Spin-off, Alliqua was not considered to be a business for accounting purposes. Accordingly, no goodwill or intangible assets were recorded as a result of the Merger. Because Private Adynxx is treated as the acquiring company, Private Adynxx's assets and liabilities are recorded at their pre-combination carrying amounts and the historical operations that are reflected in periods prior to the closing date of the Merger will be those of Private Adynxx. All share and per share amounts have been retroactively restated to give effect to the Exchange Ratio.

Private Adynxx was determined to be the accounting acquirer based upon the terms of the Merger Agreement and other factors including: (i) Private Adynxx equity holders owned approximately 86% of the voting interests of the combined company immediately following the closing of the transaction and Alliqua equity holders owned approximately 14%; (ii) directors appointed by Private Adynxx hold a majority of board seats in the combined company; and (iii) Private Adynxx management hold all key positions in the management of the combined company.

In connection with a previous modification of its Notes, the Company had computed a contingent beneficial conversion feature ("BCF") that was contingent upon the occurrence of a reverse merger. In accordance with ASC 470-20-25-6, the contingent BCF is not recognized in earnings until the contingency is resolved. Upon the date of the Merger, the full amount of beneficial conversion feature of $2.1 million was recognized as interest expense in the condensed consolidated statement of operations during the nine months ended September 30, 2019.

Dividend

In contemplation of the Merger, Alliqua declared a special cash dividend to the pre-Merger shareholders of Alliqua as of April 22, 2019. The aggregate dividend of $5,245,000 was paid on May 29, 2019.

Spin-off

On November 27, 2018, Alliqua had entered into an agreement whereby its existing operations would be distributed to existing shareholders as of a record date. With the exception of a corporate lease, substantially all of Alliqua's assets and liabilities were contributed to a subsidiary, AquaMed Technologies Inc. ("AquaMed"), whose shares were then distributed to the pre-Merger shareholders of Alliqua by way of a pro rata dividend. The dividend distribution occurred on June 21, 2019.

Because the historical periods presented prior to the merger are those of Private Adynxx, the results of AquaMed are only reflected in these financial statements from the merger date to the date of the pro rata dividend of AquaMed and are presented as discontinued operations in the condensed consolidated statement of operations.

Pro Forma Financial Information

As the only significant operations of Alliqua have been discontinued with the spin-off transaction, pro forma financial information for periods prior to the merger is not presented herein as such results are not meaningful.

Note 4. Property and Equipment, Net

Property and equipment, net, consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Furniture and fixtures	$ 29	$ 29
Office equipment	2	2
Computer equipment	18	18
Laboratory equipment	2	2
Total property and equipment	51	51
Less accumulated depreciation	(46)	(41)
Property and equipment, net	$ 5	$ 10

Depreciation expense for the three months ended September 30, 2019 and 2018 was $1,000 and $2,000, respectively, and for the nine months ended September 30, 2019 and 2018 was $5,000 and $6,000 respectively.

Note 5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Prepaid clinical trial expenses	$ 512	$ -
Equity issuance costs	740	-
Prepaid insurance	471	5
Other prepaid expenses	237	5
Total prepaid and other current assets	$ 1,960	$ 10

Note 6. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Payroll and related expenses	$ 640	$ 241
Accrued term loan final payment	608	421
Accrued clinical trial expense	26	-
Professional fees and other costs	899	195
Total accrued liabilities	$ 2,173	$ 857

Note 7. Term Loans and Convertible Promissory Notes

Term Loans

On November 24, 2015, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford, pursuant to which the Company received $3.0 million in proceeds from a Term Loan A and $2.0 million in proceeds from a Term Loan B under the Loan Agreement (collectively the "Term Loans"). The Company issued warrants to purchase 11,829 shares of common stock to Oxford in connection with the Term Loans ('*Note 10– Warrants'*). The Term Loans bear interest at a floating per annum rate equal to (a) 7.06% plus (ii) the greater of (a) the 30 day U.S. Dollar LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (b) 0.19%.

The Term Loan A was recorded at its initial carrying value of $3.0 million less debt issuance costs of approximately $141,000, and the Term Loan B was recorded at its initial carrying value of $2.0 million, less debt issuance costs of approximately $3,000. The debt issuance costs are being amortized to interest expense over the life of the Term Loans using the effective interest method.

At September 30, 2019, $1.4 million was outstanding under Term Loan A and $1.0 million was outstanding under Term Loan B. As of December 31, 2018, $2.3 million was outstanding under Term Loan A and $1.5 million was outstanding under Term Loan B.

The following modifications have been made during the nine months ended September 30, 2019:

- In January 2019, the Company and Oxford Finance agreed to amend the Loan Agreement. Oxford agreed to two months of interest-only payments followed by eight months of repayments upon delivery by February 1, 2019 of an executed term sheet for equity financing that would result in aggregate proceeds to the Company of $20.0 million. The Company was also required to place $200,000 in a segregated bank account that is subject to a blocked control agreement in favor of Oxford. Per the blocked control agreement, the account is subject to bank fees, which Oxford has agreed to have deducted from this account on a monthly basis. The funds in the segregated account were to be released upon the earlier of the consummation of a merger by March 31, 2019 or the consummation of an equity financing. The Company recorded the $200,000 as restricted cash. The maturity date of the Term Loans remained unchanged. The amendment fee amounted to $50,000. The amendment was accounted for as a debt modification.

- In May 2019, the Company and Oxford agreed to an amendment to provide consent to the Merger. This consent amended certain provisions of the Term Loans to protect Oxford's rights under the original Loan Agreement. The consent allowed Alliqua to be named as an additional borrower.

- In June 2019, the Company and Oxford agreed to amend the Loan Agreement. Oxford agreed to two months of interest-only payments and the maturity date of the Term Loans was extended two months. The amendment fee amounted to $20,000. The amendment was accounted for as a debt modification.

- In August 2019, the Company and Oxford agreed to amend the Loan Agreement. Oxford agreed to two months of interest-only payments followed by five months of scheduled repayments upon receipt by the Company of at least $500,000 by September 30, 2019 to fund operations through October 31, 2019. The maturity date of the Term Loans is March 1, 2020. The amendment was accounted for as a troubled debt restructuring.

Upon the respective dates of the debt modifications, no gain or loss was recorded, and a new effective interest rate was established based on the carrying value of the debt and the revised cash flows.

Interest expense associated with the Term Loans was $100,000 and $173,000 for the three months ended September 30, 2019 and 2018, respectively, and $436,000 and $482,000 for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, the Company was in compliance with all covenants under the Loan Agreement.

Principal payments for the Term Loans due under the loan agreement as of September 30, 2019 are due monthly beginning November 1, 2019 through the Term Loans' maturity date on March 1, 2020.

Convertible Promissory Notes

The table below reflects the principal amount of the Notes issued by the Company (in thousands):

	September 30, 2019	December 31, 2018
Convertible note payable, due on March 29, 2019 interest at 8.0% p.a.	$ -	$ 1,500
Convertible note payable, due on September 27, 2019 interest at 8.0% p.a.	-	1,500
Convertible note payable, due on December 21, 2019 interest at 8.0% p.a.	1,500	1,500
Convertible note payable, due on March 29, 2020 interest at 8.0% p.a.	1,500	-
Convertible note payable, due on April 26, 2020 interest at 8.0% p.a.	2,000	-
Convertible note payable, due on May 29, 2020 interest at 8.0% p.a.	500	-
Convertible note payable, due on July 1, 2020 interest at 8.0% p.a.	250	-
Convertible note payable, due on July 29, 2020 interest at 8.0% p.a.	350	-
Convertible note payable, due on August 30, 2020 interest at 8.0% p.a.	250	-
Total	$ 6,350	$ 4,500

Outstanding Notes

The Notes outstanding at September 30, 2019 were issued with conversion and repayment rights as described below:

(a) in the event that the Company issues and sells equity securities with proceeds to the Company of at least $5 million, on or before the maturity date, and after the closing of a reverse merger, then the outstanding principal amount of this convertible promissory note and any unpaid accrued interest will automatically convert in whole into equity securities of the same class sold in the equity financing at a conversion price equal to the cash price paid per share for equity securities in the financing,

(b) if the Company consummates a change of control while the Notes remain outstanding, the Company shall repay the holders in cash in an amount equal to 200% of the outstanding principal amount of the Notes; and

(c) in the event the Company consummates an IPO on or before the maturity date, then the outstanding principal amount of the Notes and any unpaid accrued interest will automatically convert into common stock at a conversion price equal to the per share offering price to the public for common stock in the IPO.

In July 2019 and August 2019, affiliates of Domain Partners, LLC, a significant shareholder of the Company, purchased from the Company $0.6 million and $0.3 million aggregate principal amount of Notes to fund the Company's operations. These Notes accrue simple interest on the outstanding principal amount at a rate of 8% per annum and mature in July 2020 and August 2020, respectively.

Converted Notes

In May 2019, under the terms of the then outstanding Notes, the principal and accrued unpaid interest of two Notes totaling $3.2 million were automatically converted into the Company's Series B convertible preferred stock. Upon consummation of the Merger, and subject to the terms and conditions of the Merger Agreement each outstanding share of capital stock of Adynxx, was converted into the right to receive the number of shares of the combined Company's common stock equal to the Exchange Ratio formula in the Merger Agreement. An aggregate of 367,041 post-Merger common shares were issued associated with the conversion of these Notes.

In connection with a previous modification, the Company had computed a contingent beneficial conversion feature ("BCF") that was contingent upon the occurrence of a reverse merger. In accordance with ASC 470-20-25-6, the contingent BCF is not recognized in earnings until the contingency is resolved. Upon the date of the Merger, the full amount of beneficial conversion feature of $2.1 million was recognized as interest expense in the condensed consolidated statement of operations for the nine months ended September 30, 2019.

Derivative Liability

The Company evaluated its outstanding Notes and determined that certain embedded components relating to conversion and redemption features of those contracts qualified as derivatives, which need to be separately accounted for in accordance with ASC 815. With the consummation of the Merger, several of these clauses no longer apply. However, the redemption provision upon change of control described above is an embedded feature that is required to be bifurcated.

As of September 30, 2019, the Company evaluated the fair value of the derivative liability and determined that the bifurcated derivative liability had no value because the Company estimated a zero probability of the embedded feature being triggered. As a result, the Company estimated the fair value of the derivative liability to be $0 at September 30, 2019. Similarly, the embedded derivatives that were in place at December 31, 2018 also had a fair value of $0.

Note 8. Leases

The Company leases office facilities under a non-cancelable operating lease agreement expiring on December 31, 2019. The Company also leases a corporate office facility previously utilized by Alliqua through an operating lease agreement, located in Yardley, Pennsylvania that expires in 2023. Effective February 1, 2019, this property has been subleased to The Pinnacle Health Group, Inc. through April 20, 2023 and the Company receives monthly lease payments.

Future minimum payments under non-cancellable leases as of September 30, 2019 were as follows (in thousands):

Period ending December 31	Future Commitments
2019 (remaining 3 months)	$ 116
2020	227
2021	232
2022	236
2023	80
Total future minimum lease payments	891
less: imputed interest	(148)
Total	$ 743

Total operating lease expenses for the three and nine months ended September 30, 2019 was $117,000 and $282,000, respectively, and is reflected in general and administrative expenses in the condensed consolidated statements of operations. Rent expense for the three and nine months ended September 30, 2018 was $58,000 and $174,000, respectively.

As of September 30, 2019, the Company had no leases that were classified as a financing lease. As of September 30, 2019, the Company did not have additional operating and financing leases that have not yet commenced.

During the three and nine months ended September 30, 2019, the Company recognized $61,000 and $104,000 of sublease income on its condensed consolidated statement of operations, which is recorded as an offset against general and administrative expenses.

Note 9. Redeemable Convertible Preferred Stock

At December 31, 2018, Private Adynxx had 2,034,548 shares of Series A convertible preferred stock issued and outstanding, and 1,833,387 shares of Series B convertible preferred stock issued and outstanding. During 2019, prior to the Merger, an additional 367,041 shares were issued upon conversion of convertible notes described in 'Note 7 - *Term Loans and Convertible Promissory Notes*'.

Upon the consummation of the Merger, all outstanding shares of Series A and Series B convertible preferred stock were cancelled and exchanged for shares of the Company's common stock. Following the Merger, Private Adynxx survived as a wholly-owned subsidiary of new Adynxx, Inc. and adopted a new certificate of incorporation with no shares of preferred stock authorized or outstanding. The Company has 1,000,000 shares of preferred stock authorized under its certificate of incorporation, as amended.

Note 10. Warrants

Private Adynxx had issued warrants that were previously classified as a liability as they were exercisable for preferred shares that were potentially redeemable. The fair value of the warrant liability was re-measured at each balance sheet date up through the date of the Merger with the change as other income recorded in the statements of operations.

On May 3, 2019, in connection with the closing of the Merger, each outstanding Adynxx warrant that had not previously been exercised was converted into a stock warrant to purchase shares of the Company's common stock at the Exchange Ratio and, as a result, outstanding warrants were converted into warrants to purchase an aggregate of 11,829 shares of the Company's common stock at an exercise price of $6.34 per share. As such warrants qualify for equity classification, the Company reclassified the balance of $234,000 from warrant liability to additional paid in capital. These warrants are exercisable at any time and expire in 2025 and 2026.

Additionally, upon the closing of the Merger on May 3, 2019, the Company assumed outstanding Alliqua warrants to purchase an aggregate of 38,945 shares of common stock at exercise prices ranging from $26.40 to $28.20 per share. These warrants are exercisable at any time and expire in 2022.

Note 11. Stock Options

On May 3, 2019, in connection with the closing of the Merger, each outstanding Private Adynxx stock option, whether vested or unvested, was converted into a stock option to purchase shares of the Company's common stock at the Exchange Ratio and, as a result, the Company issued options to purchase an aggregate of 690,058 shares of the Company's common stock at exercise prices ranging from $1.11 to $3.06 per share.

Additionally, at the date of the Merger, Alliqua had outstanding employee options to purchase an aggregate of 57,822 shares of the post-Merger Company's common stock at exercise prices ranging from $21.00 to $656.40 per share to former Alliqua option holders that were assumed as part of the merger. All Alliqua employees were terminated in connection with the Merger; however, such options have provisions that extend the expiration date beyond the employees' termination date.

A summary of the Company's stock option activity during the nine months ended September 30, 2019 is as follows (in thousands, except exercise prices):

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, December 31, 2018	690	$ 2.76		
Alliqua options assumed in Merger	58	289.76		
Exercised	-	-		
Expired	(17)	93.48		
Outstanding, September 30, 2019	731	$ 23.38	6.1	$ 33
Exercisable, September 30, 2019	550	$ 30.07	5.8	$ 33

A summary of the Company's stock options as of September 30, 2019 is as follows (in thousands, except exercise prices):

Range of Exercise Price	Options Outstanding		Options Exercisable		
	Weighted Average Exercise Price	Outstanding Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Exercisable Number of Options
$1.11 - $1.38	$ 1.11	73	$ 1.11	2.2	73
$1.39 - $3.05	$ 1.39	37	$ 1.39	2.9	37
$3.06 - $196.79	$ 3.06	580	$ 3.06	7.2	399
$196.80 - $656.40	$ 370.21	41	$ 370.21	0.7	41
	$ 23.38	731	$ 30.07	5.8	550

The Company did not grant any stock options to employees during the three and nine months ended September 30, 2019. Stock-based compensation expense recorded in research and development and general and administrative expenses was $68,000 and $75,000 for the three months ended September 30, 2019 and 2018, respectively, and $204,000 and $225,000 for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, unrecognized stock-based compensation expense related to employees totaled approximately $327,000, which is expected to be recognized over approximately 1.3 years.

Stock-based compensation expense recorded in exchange for services related to non-employee options was $16,000 and $0 for the three months ended September 30, 2019 and 2018, respectively, and $48,000 and $0 for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, there was no unrecognized stock-based compensation expense related to unvested non-employees stock options.

Note 12. Commitments and Contingencies

Gain on Settlement

During August 2019, the Company entered into an agreement to resolve a vendor dispute. The vendor agreed to pay the Company $635,000 (the "Settlement Amount") over a three-month period ending October 31, 2019, which is reflected as a gain on settlement in the accompanying condensed consolidated statement of operations for the three and nine months ended September 30, 2019. As of September 30, 2019, the Company has received $443,000 of the Settlement Amount, with the remaining amount reflected as prepaid expenses and other current assets on the accompanying condensed consolidated balance sheet.

Note 13. Related-Party Transactions

At September 30, 2019, the Company had $6.4 million aggregate principal amount of outstanding convertible notes issued to a significant shareholder. *'Note 7 - Term Loans and Convertible Promissory Notes'*. Interest expense associated with related party notes was $122,000 and $31,000 for the three months ended September 30, 2019 and 2018, respectively, and $325,000 and $62,000 for the nine months ended September 30, 2019 and 2018, respectively.

In connection with the Merger, Alliqua's existing CEO resigned from the company and received severance pay of $1,091,000. As such amounts were accrued by Alliqua prior to the Merger, this severance payment had no impact to our condensed consolidated statement of operations for the three and nine months ended September 30, 2019.

Note 14: Subsequent Events

In November 2019, the Company and Oxford agreed to amend the Loan Agreement. Oxford agreed to one month of interest-only payments followed by four months of scheduled repayments. The maturity date of the Term Loans is March 1, 2020. The amendment fee amounted to $30,000.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with ourunaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q, the audited consolidated financial statements and related notes thereto as of and for the years ended December 31, 2018and 2017 which are contained in ourForm 8-K/A filed with the SEC on June 10, 2019 and our other public filings.

On May 3, 2019, Private Adynxx completeda reverse merger, or the Merger, with Alliqua BioMedical, Inc., or Alliqua, and we survived as a wholly-owned subsidiary of Alliqua. Following the consummation of the Merger, Adynxx changed its name to Adynxx Sub, Inc., and Alliqua BioMedical, Inc. changed its name to Adynxx, Inc. For financial reporting purposes, Alliqua was deemed to be the acquired entity in the Merger. The following management's discussion and analysis relates to the results of operations of Adynxx, Inc. for periods subsequent to the Merger andAdynxx, the private company, for periods prior to the Merger.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management; and accounting estimates and the impact of new or recently issued accounting pronouncements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "should," "could," "predicts," "potential," "continue," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements. All forward-looking statements in this Quarterly Report on Form 10-Q are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports, including those risks outlined under the section titled "Item 2A. Risk Factors" found elsewhere in this report. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties and other information contained in the reports we file with or furnish to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement.

Additionally, there may be other risks that are otherwise described from time to time in the reports that we file with the Securities and Exchange Commission. Any forward-looking statements in this report should be considered in light of various important factors, including the risks and uncertainties listed above, as well as others.

Overview

We are a clinical stage biopharmaceutical company focused on the development of a new class of therapeutics called transcription factor decoys and bringing to market novel, disease-modifying products for the treatment of pain and inflammation. Transcription factor decoys are short strands of DNA that specifically bind to and block the activity of their target transcription factors. Transcription factors are proteins that specifically bind to the regulatory regions of one or more target genes and regulate the expression of those genes. Since our founding in 2007, we have leveraged our AYX platform of proprietary transcription factor decoys to identify and develop novel product candidates designed to modify the course of pain. We believe that our transcription factor decoy technology can transform the treatment of pain, and going forward has the potential to be applied to additional disease states. We plan to continue advancing our AYX platform programs while simultaneously developing new transcription factor decoy candidates, collaborating with twoXAR, our artificial intelligence-driven drug discovery partner, and evaluating in-licensing opportunities in order to expand our pipeline and leverage our business development, clinical development and regulatory expertise.

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception to September 30, 2019, we have raised net cash proceeds of approximately $63 million, primarily through the sale of equity securities, receipts of proceeds from a strategic collaboration, government grants, issuance of Notes, and gross proceeds from the Oxford term loans.

In December 2018, we received a grant from the National Institute on Drug Abuse, or NIDA, part of the National Institutes of Health, or NIH, the NIH grant, to support the clinical development of our lead product candidate, brivoligide. NIH grants provide funds for certain types of expenditures in connection with research and development activities over a contractually defined period. The maximum funding to be available under this grant for qualified expenditures over the next two years is expected to be approximately $5.7 million. We started drawing from this NIH grant in February 2019 and recognized $1.9 million and $0 as grant reimbursement contra-expense in our operating expenses for the nine months ended September 30, 2019 and 2018, respectively. We intend to continue to evaluate pursuing additional government grant opportunities on a case-by-case basis. In September 2019, we received a Notice of Award from the National Institute on Neurological Disease and Stroke, or NINDS, part of the NIH, for up to approximately $0.6 million to be paid over 12 months to support our planned preclinical studies of AYX2. The funds will become available after approval from the Office of Laboratory Animal Welfare, or OLAW, of the planned preclinical studies for AYX2, and we have not yet drawn from this NIH grant. We have incurred operating losses in each year since inception, with the exception of 2014, when we received a $20.0 million option payment as part of a strategic collaboration, which was subsequently terminated in 2014. Our net losses were $1.9 million and $1.5 million for the three months ended September 30, 2019 and 2018, respectively, and $9.0 million and $4.5 million, for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $46.3 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates and add personnel necessary to operate as a public company with an advanced clinical pipeline of products. In addition, operating as a publicly traded company involves the hiring of additional financial and other personnel, upgrading our financial information systems and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval of any of our product candidates.

Our current capital resources are insufficient to fund our planned operations for a 12-month period, and therefore, raise substantial doubt about our ability to continue as a going concern. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

Basis of Presentation

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research and development, such as the development of our product candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- expenses incurred under agreements with consultants and clinical trial sites that conduct research and development activities on our behalf;
- laboratory and vendor expenses related to the execution of clinical trials;
- contract manufacturing expenses, primarily for the production of clinical supplies; and

- internal costs that are associated with activities performed by our research and development organization. These costs are not separately allocated by product candidate as we typically use our employee resources across various research and development activities. Unallocated internal research and development costs consist primarily of:

    - personnel costs, which include salaries, benefits and stock-based compensation expense; and

    - regulatory expense related to development activities.

The largest component of our operating expenses has historically been the investment in research and development activities. However, we do not allocate internal research and development costs, such as salaries, benefits, stock-based compensation expense and indirect costs to product candidates on a program-specific basis. The following table shows our research and development expenses by program (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Direct research and development expenses by program:		
AYX Platform	$ 1,517	$ 120
ADYX-005 TKA	1,184	-
ADYX-006 Mastectomy	1,161	-
twoXar Platform	75	-
ADYX-004 TKA	2	92
Internal research and development expenses	1,273	1,581
	$ 5,212	$ 1,793

We expect research and development expenses will increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approvals, which will require a significant investment in regulatory support and contract manufacturing. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fees and/or milestone payments.

In December 2018, we received a NIH grant to support the clinical development of our lead product candidate, brivoligide. The grant is expected to provide approximately $2.8 million in funding in 2019 that will support research and development activities for the ADYX-006 Mastectomy study. We record qualified expenses reimbursable under the NIH grant as grant reimbursements, a contra operating expense.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, intellectual property rights, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

Our general and administrative expenses consisted of personnel-related costs, professional fees for legal, consulting, audit and tax services, overhead expenses, such as rent, equipment depreciation, insurance and utilities, and other general operating expenses not otherwise included in research and development expenses.

We expect to incur additional expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and standards applicable to companies listed on the over-the-counter market with securities registered under the Exchange Act, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative headcount to support the growth of our business and operate as a public company.

Grant Reimbursements

We account for reimbursements of qualified grant related research and development expenses in accordance with the guidance provided by the Financial Accounting Standards Board, or FASB, in the Accounting Standards Update (ASU) 2018-08, "*Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*," or ASU 2018-08, which it adopted in January 2019. Based on this guidance, we determined that reimbursements of qualified expenses per the terms of the grant, met the definition of a 'conditional contribution' (versus an exchange contract) because (i) we have limited discretion in the way the funds may be spent, which creates a barrier to entitlement, and (ii) the grant contains provisions that release the awarding agency from the obligation to transfer funds that are not expended at the time the award is terminated.

We recognize the grant reimbursements as a contra operating expense in the period in which the related costs are incurred and the related services are rendered, provided that the applicable performance obligations under the government grants have been met.

Interest Income (Expense), Net

Interest income (expense), net, consists primarily of cash interest expense on the Oxford term loans, or Term Loans, and non-cash interest expense and amortization of debt issuance and debt discount costs related to the Term Loans and the debt discounts on the issuance of Notes, as well as the recognition of $2.1 million of a contingent beneficial conversion feature that was recognized upon the date of the Merger. Debt discount is accreted to interest expense over the debt borrowing term.

Other Income

Other income consists primarily of gains and losses resulting from the revaluation of our preferred stock warrant liabilities and convertible debt derivative liabilities, both of which are revalued at the end of each reporting period and any change in fair value recorded as a component of other income or expense.

We had preferred stock warrants related to Term Loans as well as convertible debt derivatives relating to the issuance of Notes. Both the warrants and Notes derivatives were recorded as a liability, with an offsetting amount recorded as debt discount. The preferred stock warrants were converted into warrants to purchase shares of common stock upon the closing of the Merger. We recorded adjustments to the fair value of the convertible debt derivative liability, as applicable, for the duration that they were outstanding.

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we maintained a full valuation allowance on the net deferred tax assets at September 30, 2019 and December 31, 2018. We intend to maintain a full valuation allowance on the federal and state deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

Summary of Significant Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. [Refer to Note 1, "Summary of Significant Accounting Policies" in Part I, Item 1 of this Form 10-Q for a description of the significant accounting policies and methods used in the preparation of the Company's condensed consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018 (in thousands)

	Three months ended September 30,		
	2019	2018	Dollar change
Operating expenses			
Research and development	$ 1,986	$ 524	$ 1,462
General and administrative	1,037	810	227
Grant reimbursements	(716)	-	(716)
Gain on settlement	(635)	-	(635)
Total operating expenses, net	1,672	1,334	338
Loss from operations	(1,672)	(1,334)	(338)
Interest expense, net	(223)	(322)	99
Other income (expense), net	-	151	(151)
Loss from continuing operations	(1,895)	(1,505)	(390)
Loss from discontinued operations	-	-	-
Net loss	$ (1,895)	$ (1,505)	$ (390)

Research and Development

Research and development expenses increased by $1.5 million to $2.0 million for the three months ended September 30, 2019, from $0.5 million for the three months ended September 30, 2018. The increase was primarily due to $1.0 million in connection with start-up activities related to our planned Phase 2 ADYX-005 TKA and the Phase 2 ADYX-006 mastectomy clinical trials and $0.6 million related to the initiation of drug supply manufacturing with Avecia, partially offset by a $0.1 million reduction in salaries and benefits from the resignation of an employee and other minor cost changes.

General and Administrative

General and administrative expenses increased by $0.2 million to $1.0 million for the three months ended September 30, 2019, from $0.8 million for the three months ended September 30, 2018. This increase was due to $0.2 million in other general and administrative costs, including insurance, associated with us being a public company.

Grant Reimbursements

Beginning in February 2019, we started to receive payments from a NIH grant to support the clinical development of our lead product candidate, brivoligide. In the three months ended September 30, 2019, we recorded $0.7 million of grant reimbursements relating to qualified expenses incurred under the terms of the NIH grant.

Gain on Settlement

During August 2019, we entered into an agreement to resolve a vendor dispute. The vendor agreed to pay us $0.6 million which is reflected as a gain on settlement in the accompanying condensed consolidated statement of operations.

Interest Expense

Interest expense decreased by $0.1 million to 0.2 million for the three months ended September 30, 2019, from $0.3 million for the three months ended September 30, 2018. This decrease was primarily due to extinguishment of debt discount upon modification of debt terms.

Comparison of the Nine Months Ended September 30, 2019 and 2018 (in thousands)

	Nine months ended September 30,		
	2019	**2018**	**Dollar change**
Operating expenses			
Research and development	$ 5,212	$ 1,793	$ 3,419
General and administrative	3,354	2,102	1,252
Grant reimbursements	(1,914)	-	(1,914)
Gain on settlement	(635)	-	(635)
Total operating expenses, net	6,017	3,895	2,122
Loss from operations	(6,017)	(3,895)	(2,122)
Interest expense, net	(2,864)	(767)	(2,097)
Other income (expense), net	(94)	211	(305)
Loss from continuing operations	(8,975)	(4,451)	(4,524)
Loss from discontinued operations	(58)	-	(58)
Net loss	$ (9,033)	$ (4,451)	$ (4,582)

Research and Development

Research and development expenses increased by $3.4 million to $5.2 million for the nine months ended September 30, 2019, from $1.8 million for the nine months ended September 30, 2018. The increase was primarily due to $2.2 million in connection with start-up activities related to the Phase 2 ADYX-005 TKA and the Phase 2 ADYX-006 Mastectomy clinical trials and $1.4 million related to the initiation of drug supply manufacturing with Avecia, partially offset by a $0.2 million in salaries and benefits associated with the resignation of one employee.

General and Administrative

General and administrative expenses increased by $1.3 million to $3.4 million for the nine months ended September 30, 2019, from $2.1 million for the nine months ended September 30, 2018. This increase was primarily due to an increase of $0.9 million in legal and professional service costs incurred in connection with the Merger and preparation to be a public company, and an increase of $0.4 million in other general and administrative costs, including insurance, associated with us being a public company.

Grant Reimbursements

Beginning in February 2019, we started to receive payments from a NIH grant to support the clinical development of our lead product candidate, brivoligide. In the nine months ended September 30, 2019, we recorded $1.9 million of grant reimbursements relating to qualified expenses incurred under the terms of the NIH grant.

Gain on Settlement

During August 2019, we entered into an agreement to resolve a vendor dispute. The vendor agreed to pay us $0.6 million which is reflected as a gain on settlement in the accompanying condensed consolidated statement of operations.

Interest Expense, Net

Interest expense, net, increased by $2.1 million to $2.9 million during the nine months ended September 30, 2019, from $0.8 million during the nine months ended September 30, 2018. The increase was primarily attributable to the recognition of $2.1 million associated with the beneficial conversion feature recognized upon the modification and conversion of two Notes.

Loss from Discontinued Operations

Loss on discontinued operations relates to the AquaMed business that was incurred from the date of the Merger to its spin-off that occurred on June 21, 2019.

Liquidity and Capital Resources

We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will continue to incur increasing losses in the foreseeable future. As stated above, we also expect that our current capital resources will be insufficient to fund our planned operations for a 12-month period. Therefore, we will need to raise additional capital to fund our operations, which may be through the issuance of additional equity, and potentially through the incurrence of additional debt. In addition, we may be required to raise additional capital in the future to service our indebtedness, including outstanding indebtedness that will become due and payable during fiscal year 2019, and make necessary capital expenditures. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts and our ability to refinance outstanding indebtedness before the applicable maturity date. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates. In addition, if we default under the loan and security agreement, or the Loan Agreement, with Oxford, Oxford will have the ability to exercise its rights as collateral agent to take possession and dispose of the collateral securing the indebtedness under the Loan Agreement, which collateral includes all of our property including our intellectual property.

Beginning in February 2019, we started to receive payments from a NIH grant to support the clinical development of our lead product candidate, brivoligide. While these payments will offset certain qualifying expenses incurred on this research and development program, it will not be adequate to cover other expenses expected to be incurred for research, development, general and administrative expenses.

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize any of our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for, our product candidates. Subject to obtaining regulatory approvals of any of our product candidates, we anticipate that we will need substantial additional funding in connection with our continuing operations. Further, we expect to continue to incur additional costs associated with operating as a public company following the Merger.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowings, receipt of proceeds from government grants, and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table shows a summary of our cash flows for each of the periods shown below (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Net cash used in operating activities	$ (4,767)	$ (4,649)
Net cash used in investing activities	-	(2)
Net cash provided by financing activities	3,409	2,110
Net decrease in cash and cash equivalents	(1,358)	(2,541)
Cash, cash equivalents and restricted cash at beginning of period	1,942	4,356
Cash, cash equivalents and restricted cash at end of period	$ 584	$ 1,815

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2019 was $4.8 million, consisting of a net loss of $9.0 million, which was offset by non-cash charges of $3.2 million primarily for non-cash interest expense on Notes, stock-based compensation expense, accretion of the charge due upon maturity of debt, and amortization of right of use assets, and a net increase in cash resulting from changes in operating assets and liabilities of $1.0 million. The change in our net operating assets and liabilities included cash generated from an increase in accounts payable of $2.2 million and an increase of $1.0 million for accrued liabilities, both of which were due primarily to an increase in legal, accounting and other professional fees and expenses incurred in connection with the Merger and preparation to be a public company, which was offset by cash used due to an increase in prepaid expense of $1.9 million primarily related to clinical trial activity and $0.2 million of lease liability payments.

Cash used in operating activities for the nine months ended September 30, 2018 was $4.7 million, consisting of a net loss of $4.5 million, which was offset by noncash charges of $0.5 million primarily for stock-based compensation expense, accretion of the charge due upon maturity of debt and amortization of debt discount and debt financing costs. In addition, $0.7 million of cash was consumed resulting from changes in operating assets and liabilities. The change in our net operating assets and liabilities was due primarily to a decrease in accounts payable of $0.6 million related to the completion of the ADYX-004 clinical trial initiated in 2017 and a decrease of $0.1 million due to the reduction of accrued liabilities relating to the ADYX-004 clinical trial.

Cash Flows from Investing Activities

Cash used in investing activities for all periods presented was nominal.

Cash Flows from Financing Activities

During the nine months ended September 30, 2019, net cash provided by financing activities was $3.4 million, consisting of $4.8 million proceeds from the issuance of Notes, offset by $1.4 million used to repay principal of the Term Loans.

During the nine months ended September 30, 2018, net cash used in financing activities was $2.1 million consisting of $3.0 million proceeds from the issuance of Notes, offset by $0.9 million used to repay principal under the Term Loans.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2019 (in thousands):

	Total	Less than 1 Year	1 - 3 Years	3-5 Years	More Than 5 Years
Term loan principal and interest[(1)]	$ 3,104	$ 3,104	$ -	$ -	$ -
Convertible promissory notes and interest[(2)]	6,859	6,859	-	-	-
Operating lease commitments [(3)]	891	287	465	139	-
	$ 10,854	$ 10,250	$ 465	$ 139	$ -

(1) Reflects principal, interest payments through maturity and final balloon payment due to Oxford under the Loan Agreement. The interest rate under the Loan Agreement is floating and future interest payments are estimated based upon the September 2019 interest rate.

(2) Reflects principal and accrued interest under outstanding convertible promissory notes through maturity. The notes automatically convert into shares of common stock upon the closing of a qualified equity financing.

(3) We lease our office space under a non-cancellable long-term operating lease. Reflects cash payments due under the remaining term of the operating lease, and amounts are not adjusted for imputed interest related to the lease liability.

Convertible Notes

In May 2019, upon the closing of the Merger, $3.0 million principal amount of Notes, plus $203,000 of cumulative accrued but unpaid interest, were converted into 367,041 shares of preferred stock, which were converted into shares of common stock upon completion of the Merger.

As of September 30, 2019, $6.4 million aggregate principal amount remained outstanding under outstanding Notes.

Term Loans

In November 2015, we entered into the Loan Agreement with Oxford pursuant to which Oxford agreed to lend us up to $10.0 million principal amount issuable in three tranches, or the Term Loans, of which $5.0 million had been drawn as of September 30, 2019. The Term Loans will mature on November 1, 2019. The Loan Agreement has been amended several times. We have the option to prepay all, but not less than all, of the borrowed amounts, provided that we will be obligated to pay a prepayment fee. The Term Loans bear interest at a floating per annum rate equal to (i) 7.06% plus (ii) the greater of (a) the 30-day U.S. Dollar LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (b) 0.19%. We will be required to make a final payment of 4.25% of the funded amount, payable on the earlier of (i) the maturity date or (ii) the prepayment of the Term Loans. Our obligations under the Loan Agreement are secured by a perfected first-priority lien on all of our assets including our intellectual property. In connection with the Merger, Alliqua was named as an additional borrower under the Loan Agreement. As of September 30, 2019, we were in compliance with all covenants under the Loan Agreement.

In January 2019, we and Oxford amended the Loan Agreement to provide for two months of interest-only payments followed by eight months of repayments. We also placed $200,000 in a segregated bank account that is subject to a blocked control agreement in favor of Oxford. Per the blocked control agreement, the account is subject to bank fees, which Oxford has agreed to have deducted from this account on a monthly basis. The funds in the segregated account will be released upon the closing of this offering. The amendment fee was $50,000. The amendment was accounted for as a debt modification.

In May 2019, we and Oxford agreed to an additional amendment to provide consent to the Merger. This consent amended certain provisions of the term loan to protect Oxford's rights under the original Term Loan agreement. The consent allowed Alliqua to be named as an additional borrower.

In June 2019, we and Oxford agreed to amend the Loan Agreement. Oxford agreed to two months of interest-only payments and the maturity date of the Term Loans was extended two months. The amendment fee was $20,000. The amendment was accounted for as a debt modification.

In August 2019, we and Oxford agreed to amend the Loan Agreement. Oxford agreed to two months of interest-only payments followed by five months of repayments upon receipt by us of at least $500,000 by September 30, 2019 to fund operations through October 31, 2019. The maturity date of the Term Loans is March 1, 2020. The amendment was accounted for as a troubled debt restructuring.

In connection with the Loan Agreement, we issued warrants to purchase our preferred stock to Oxford. Upon the closing of the Merger, these warrants were converted into warrants to purchase 11,829 shares of our common stock at an exercise price of $6.34 per share. The warrants are immediately exercisable and expire ten years from the issuance date.

Other Contracts

We enter into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing and other general and administrative services. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Recently Adopted Accounting Pronouncements

Lease Accounting

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02. ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months on the balance sheet. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We adopted the new standard on January 1, 2019 and used the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We have elected the package of practical expedients permitted in ASC Topic 842. Accordingly, we accounted for our existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs before transition adjustments (as of December 31, 2015) would have met the definition of initial direct costs in ASC Topic 842 at lease commencement.

As a result of the adoption of the new lease accounting guidance, we recognized on January 1, 2019 (a) a lease liability of approximately $227,000, which represents the present value of the remaining lease payments of approximately $239,000, discounted using our incremental borrowing rate of 9.41%, and (b) a right-of-use asset of approximately $227,000 which represents the lease liability of $227,000. The most significant impact was the recognition of right-of-use, or ROU, assets and lease obligations on the balance sheet for operating leases. This standard did not have a material impact on our operating results or cash flows from operations.

Recent Accounting Pronouncements Not Yet Effective

In August 2018, the FASB issued ASU No. 2018-13, *Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820).* The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. This ASU is effective for fiscal years beginning after December 15, 2019 including interim periods within that fiscal year, with early adoption permitted. We are currently assessing whether these amendments will have a material effect on our financial statements.

Off-Balance Sheet Arrangements

During the nine months ended September 30, 2019 and the year ended December 31, 2018, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This item has been omitted as we qualify as a smaller reporting company.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Controller, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our disclosure controls and procedures were designed to provide reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Controller concluded that our disclosure controls and procedures are not effective at a level that provides reasonable assurance.

Remediation Efforts on Previously Identified Material Weakness

During the audit of our financial statements for the year ended December 31, 2018 and in connection with the preparation of interim financial statements for the first three quarters of 2019, a material weakness was identified in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. The material weakness that was identified related to our inability to prepare accurate financial statements, resulting from a lack of adequate accounting personnel to timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with GAAP, including the recording of convertible note and related disclosures, and as a result of the previously disclosed restatement of our consolidated statements of operations for the three and six months ended June 30, 2019 and 2018.

We are implementing measures designed to improve our disclosure controls and procedures and internal control over financial reporting to address the underlying causes of this material weakness, including hiring key accounting personnel and third-party consultants. Our remediation efforts are ongoing. However, our efforts to remediate this material weakness may not be effective or prevent any future material weakness or significant deficiency in our internal control over financial reporting. If our efforts are not successful, or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

Changes in Internal Control over Financial Reporting

We are currently in the process of adding additional controls over financial reporting, including the engagement of third-party consultants to assist with our financial reporting process. We are also currently evaluating the impacts of such control changes to our overall system of internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not presently party to any material legal proceedings. From time to time we may be involved in claims arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us in excess of established reserves, in the aggregate, not to be material to our consolidated financial condition or cash flows. However, losses may be material to our operating results for any particular future period, depending on the level of income for such period.

ITEM 1A. RISK FACTORS

RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred losses since our inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical development-stage biopharmaceutical company with a limited operating history. On May 3, 2019, we completed the Merger with Alliqua BioMedical, Inc., and we survived as a wholly-owned subsidiary of Alliqua. Following the consummation of the Merger, Adynxx changed its name to Adynxx Sub, Inc., and Alliqua BioMedical, Inc. changed its name to Adynxx, Inc. Adynxx was deemed to be the accounting acquirer in the Merger and the historical financial statements of Private Adynxx are deemed to be the historical financial statements of the combined company. We have incurred net losses for the past several years, including net losses of $9.0 million, $6.0 million and $11.6 million for the nine months ended September 30, 2019 and the years ended December 31, 2018 and 2017, respectively. As of September 30, 2019, we had an accumulated deficit of $46.3 million.

As of September 30, 2019, we had $14.3 million in current and long-term liabilities. Our management concluded that there is substantial doubt about our ability to continue as a going concern. The audit report to our financial statements for the year ended December 31, 2018, also includes an explanatory paragraph related to our ability to continue as a going concern. The doubts concerning our ability to continue as a going concern may impact our ability to obtain financing on reasonable terms or at all. As of September 30, 2019, we had cash and cash equivalents of $0.3 million.

We have devoted substantially all of our financial resources to identifying and developing our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities, payments associated with strategic collaborations, secured loan agreements and convertible notes. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect losses to increase as we continue Phase 2 development of our lead program brivoligide in two models of postoperative pain and potentially advance additional product candidates through investigational new drug, or IND, enabling activities and into clinical development. While we have not yet commenced pivotal clinical trials for any product candidate and it may be several years, if ever, before we complete pivotal clinical trials and have a product candidate approved for commercialization, we expect to invest significant funds into these clinical candidates to determine the potential to advance these compounds to regulatory approval.

If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, hospital formulary access, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for our product candidates, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates;
- advance our programs into larger, more expensive clinical trials;
- initiate additional nonclinical, clinical, or other studies for our product candidates;
- identify and develop potential commercial opportunities, such as reduction in postoperative pain for patients scoring ≥16 on the Pain Catastrophizing Scale, or PCS, for the brivoligide product candidate;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- continue manufacturing our product candidates and plan for scale-up of outsourced manufacturing capabilities as we commence additional clinical trials for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We have never generated any revenue from product sales and may never be profitable

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of our product candidates;
- obtaining regulatory and marketing approvals for our product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;

- marketing, launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of our product candidates as treatment options;
- addressing any competing products;
- protecting and enforcing our intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining reimbursement or pricing for our product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. We will have to develop or acquire commercial-scale manufacturing capabilities in order to continue development and potential commercialization of our product candidates. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

Servicing our indebtedness requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial indebtedness.

As of September 30, 2019, our total current and long-term liabilities balance was $14.3 million, of which $2.4 million was secured indebtedness, collateral for which includes, but is not limited to, our intellectual property rights. Our ability to make scheduled payments of the principal, to pay interest on, to refinance the secured loan agreement with Oxford, or the Loan Agreement, or Notes or to make cash payments in connection with any conversion of the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control and ability to raise additional capital. We may not be able to raise sufficient capital or generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives if they are available to us based on the terms of the instruments and agreements governing the indebtedness, such as restructuring indebtedness or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. If we default under the Loan Agreement, Oxford will have the ability to exercise its rights as collateral agent to take possession and dispose of the collateral securing the indebtedness under the Loan Agreement, which collateral includes all of our property, including our intellectual property. Our business, financial condition and results of operations could be substantially harmed as a result of any such foreclosure.

Despite our current indebtedness levels, we may still incur substantially more indebtedness or take other actions which would intensify the risks discussed above.

Despite our current indebtedness levels, and the restrictions we are under based on the terms of the Loan Agreement from incurring additional senior indebtedness, we may be able to incur substantial additional indebtedness in the future, subject to any restrictions contained in our then-existing debt instruments, some of which may be secured indebtedness, however the terms of such indebtedness may not be commercially attractive, if available.

We face risks related to government funded awards. If NIDA/NIH or NINDS/NIH were to eliminate, reduce or delay funding from these awards, this would have a significant negative impact on the brivoligide program.

We are substantially dependent upon awards from NIDA/NIH and NINDS/NIH for the costs related to the planned brivoligide Phase 2 and Phase 3 mastectomy model studies and the development of AYX2, respectively. If NIDA/NIH or NINDS/NIH were to eliminate, reduce or delay the funding for either or both of these awards or disallow some of our incurred costs, we would have to obtain additional funding for continued development or regulatory registration for brivoligide and AYX2 or significantly delay, reduce or stop the development effort. In contracting with NIDA/NIH and NINDS/NIH, we are subject to various U.S. government contract requirements which may limit reimbursement or if we are found to be in violation could result in contract termination. If the U.S. government terminates our award for its convenience, or if we default by failing to perform in accordance with the award schedule and terms, significant negative impact on our cash flows and operations could result.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

To the extent that we raise additional capital through the sale of equity, debt or other securities convertible into equity, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions, or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially affect our business, financial condition, and results of operations.

Risks Related to the Development of Our Product Candidates

We are heavily dependent on the success of our lead product candidate, brivoligide, which is in the early stages of clinical development, and our other product candidates, which are in pre-clinical development. We cannot give any assurance that we will generate data sufficient to receive regulatory approval, which will be required before any of our product candidates can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to identify and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more product candidates. We currently generate no revenue from sales of any drugs, and we may never be able to develop or commercialize a product candidate.

Our product candidate brivoligide, which is currently in Phase 2 of clinical development, is being developed for the reduction of postoperative pain in patients scoring ≥16 on the PCS. We have not prospectively demonstrated a statistically significant clinical benefit in this patient population for the primary endpoint in any clinical trial and may not be able to do so. Furthermore, the U.S. Food and Drug Administration, or the FDA, has not previously granted an indication for the reduction of postoperative pain in patients scoring ≥16 on the PCS. Additionally, in order to obtain an indication for the reduction of postoperative pain without restriction by type of surgical procedure, we intend to study brivoligide in pivotal trials in one orthopedic and one soft-tissue model of postoperative pain. We have studied brivoligide to date in total knee arthroplasty, or TKA, an orthopedic model of postoperative pain, and intend to study brivoligide in mastectomy with immediate tissue expander or implant placement, or mastectomy, as a soft-tissue model of postoperative pain. Failure to demonstrate efficacy in both an orthopedic and soft-tissue model of postoperative pain may limit the likelihood of FDA approval for brivoligide for postoperative pain, may limit approval to a subset of surgical procedures, and may limit the addressable patient population and related commercial opportunity. Further, we may not be able to replicate or develop additional data to satisfy regulatory requirements for approval. Our other product candidate, AYX2, has not yet been evaluated in clinical trials and may fail to show the desired safety and efficacy during clinical development. There can be no assurance that the data that we develop for our product candidates in their planned indications will be sufficient to obtain regulatory approval.

Our current product candidates are for the treatment of pain. The evaluation of pain therapeutics often relies upon patient-reported outcomes of pain, such as the Numerical Rating Scale, or NRS, as clinical trial endpoints. While these endpoints are well-validated and accepted by the FDA and comparable foreign authorities for evaluation of efficacy of product candidates for the treatment of pain, there may be increased variability associated with these patient-reported outcomes as compared to objective measures used in evaluation of efficacy for product candidates treating other disease states. If these patient-reported endpoints are associated with increased variability in future studies, the data generated may not be sufficient to obtain regulatory approval.

In addition, none of our product candidates have advanced into a pivotal study for their proposed indications and it may be years before such studies are initiated and completed, if at all. We are not permitted to market or promote any of our product candidates before they receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Our research and development is focused on discovering and developing novel drugs based on transcription factor decoys, and the approach we are taking to discover and develop drugs is not proven and may never lead to marketable products.

The discovery and development of drugs based on transcription factor decoys is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing differentiated product candidates based on these discoveries is both preliminary and limited, and has not led to products which have obtained regulatory approval by the FDA or comparable foreign authorities. Therefore, we do not know if our approach will be successful. Failure by any transcription factor decoy, including those currently being developed by us, would adversely impact this platform technology.

In addition, our product candidates are all based on a single platform technology. If we were required to discontinue development of brivoligide because the related trials are unsuccessful or do not demonstrate sufficiently positive results to continue development of brivoligide, development of our other product candidates may be harmed. Moreover, if we decide to leverage any success with brivoligide to develop our other product candidates reliant on our platform technology, we may not be successful in such efforts. In any such event, our business will be adversely impacted.

Our research and development is focused on discovering and developing non-opioid therapies to treat pain. We are not developing our product candidates to address opioid dependence, and any potential impact these therapies may have on opioid usage is speculative and may never be supported by clinical data.

Our product candidates are being developed for the treatment of pain. There can be no assurance that any of these product candidates will have any impact on potential opioid usage in patients who use our product candidates, if approved. There remains significant uncertainty regarding the assessment of opioid-sparing outcomes in clinical trials of product candidates addressing pain as well as the clinical relevance of any such results. Further, there is no clear guidance from regulators on the design or endpoints of clinical trials intended to evaluate pain and related opioid usage and what clinical data, if any, would be necessary to support potential claims of reduced opioid usage or opioid-sparing effects. As a result of this uncertainty, we cannot assess, and can provide no assurance of, the potential impact, if any, that our product candidates may have on opioid usage for pain or as analgesic therapy. In addition, we have not evaluated, and do not intend to evaluate, the potential effect of our product candidates on opioid dependence.

We have yet to present the current clinical data to the relevant regulatory authorities to give an opinion on the clinical development pathway for brivoligide.

We plan to present the clinical and non-clinical data sets for brivoligide to the FDA and relevant foreign regulatory authorities after completion of the planned Phase 2 studies at an End of Phase 2 meeting or receipt of scientific advice from the European Medicines Agency, or EMA, as applicable. Until the results of these meetings are known and documented, there can no assurance as to what requirements may be imposed for filing a New Drug Application, or NDA, or Marketing Approval in the EMA for brivoligide. We are currently relying on opinions from experts and regulatory precedents to design our development program. It is possible that the official position of the applicable regulatory authorities will be substantially different from the advice we have received. Any such difference could increase both the time and cost required to obtain the necessary regulatory approvals for brivoligide, which may in turn limit or prohibit its further development, resulting in a material harm to our business, financial condition, results of operations and prospects.

Even if we successfully complete the necessary preclinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the regulatory approval may be for a more narrow indication than we seek.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, size or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with the use of and definition of one orthopedic and one soft-tissue surgical model of postoperative pain as appropriate for approval for general postoperative pain;
- the FDA does not currently have published guidance on the requirements for a general postoperative pain indication and may publish guidance that is not in alignment with our current clinical development plans, which may cause us to alter development plans, thereby increasing the costs and time required to complete clinical development of brivoligide;
- the FDA or comparable foreign regulatory authorities may disagree with the use of the PCS as a tool for patient selection for treatment with brivoligide;
- the population studied in our clinical trials may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or foreign jurisdictions;
- the FDA or comparable foreign regulatory authorities may find failures in our manufacturing processes, validation procedures and specifications, or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies that may delay or limit our ability to obtain regulatory approval for our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our NDA or other applicable regulatory submissions insufficient for approval.

The lengthy and uncertain regulatory approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the relevant regulatory authorities may not complete their review processes in a timely manner, may issue a complete response letter, or ultimately, may not approve our product candidates. In addition, we may experience delays or rejections if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of data obtained from preclinical and clinical testing could delay, limit or prevent the receipt of marketing approval for a product candidate.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and earlier clinical trials may not be predictive of future results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in limited numbers of clinical sites. We will have to conduct larger studies in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. 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 despite promising results in earlier, smaller clinical trials. We have spent several years conducting clinical studies for our lead product candidate and anticipate that we will continue conducting clinical studies for a few more years. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our product candidates.

Interim, "top-line," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as additional analyses are conducted, and as the data are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line," or preliminary data from our clinical studies. Interim data are data analyzed before completion of enrollment of a clinical trial, and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. "Top-line" or preliminary data from our clinical studies refer to the initial planned analyses of primary and certain key secondary endpoints from clinical trials after enrollment has been completed and the data from the study database is locked. These data remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, "top-line" and preliminary data should be viewed with caution until the final data are available. Significant changes between preliminary, "top-line," or interim data and final data could harm our business.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients scoring ≥16 on the PCS who are undergoing the procedures we intend to use as our models of postoperative pain for testing of brivoligide. We may also find it difficult to enroll patients in surgical models that are performed under general anesthesia due to the intrathecal route of administration of brivoligide. Difficulty in enrolling patients could delay or prevent the completion of clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is essential to their success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in completion of our clinical trials if we encounter difficulties in enrollment.

In future clinical trials of brivoligide, we will be evaluating brivoligide using surgical models including but not limited to TKA and mastectomy. While we have successfully completed enrollment in three Phase 2 studies of postoperative pain following TKA to date within projected timelines, we may not be able to do so successfully in the future. We have never conducted a study using the mastectomy model of postoperative pain, and may not meet projected enrollment timelines. Some competitors have ongoing clinical trials for product candidates that use the same surgical models as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in competitors' clinical trials.

The eligibility criteria of our planned clinical trials may further limit the availability of suitable clinical trial participants as we expect to require that patients have specific measurable characteristics or meet certain criteria to assure that they are appropriate for inclusion in our clinical trials. In future clinical trials of brivoligide, we will be evaluating brivoligide in patients scoring ≥16 on the PCS. Approximately one-third of individuals score ≥16 on the PCS, however if this rate is not reflected in patient populations at the clinical trial sites, we may have fewer patients eligible for enrollment than expected. In addition, we may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials in a timely fashion because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the willingness of patients to receive an intrathecal injection if undergoing a surgical procedure typically performed under general anesthesia, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting studies and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site;
- refusal to permit the conduct of a clinical trial by regulatory authorities, after review of an IND, or equivalent foreign application or amendment;
- delays in recruiting qualified patients in our clinical trials;
- failure by clinical sites or our CROs or other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's Good Clinical Practice requirements, or GCP, or applicable foreign regulatory guidelines;
- high patient drop-out rate in our clinical trials;
- occurrence of adverse events, or AEs, associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials, delay regulatory approval by the FDA or comparable foreign regulatory authorities or, even if approved, result in restrictive labelling of our products. We will continue to evaluate our product candidates in additional clinical trials, and there is no guarantee that severe side effects will not be identified.

Brivoligide targets Early Growth Response 1, or EGR1, a transcription factor that has a role in memory consolidation within the hippocampus. There is a potential risk of transient alteration in memory function with brivoligide if sufficient material is distributed to the brain. This risk has been evaluated in preclinical studies and in the clinical trials conducted to date, but has not been observed; however, studies using the mastectomy model will involve movement of the brivoligide injection to the upper regions of the spinal canal which may involve increased risk of brain exposure and possible transient cognitive or memory dysfunction.

Brivoligide is intended to prevent or reduce exacerbated pain following surgery and not to mask, numb or otherwise alter a patient's normal response to pain. However, we have not conducted studies on or otherwise evaluated any masking effect of brivoligide on a patient's pain response function. If patients, physicians or other healthcare providers consider brivoligide to alter patients' normal pain response in a manner that would be considered detrimental to recovery, that would be considered an undesirable side effect and would harm our ability to develop brivoligide and future market acceptance of brivoligide.

Additionally, even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- withdrawal of regulatory approvals of such products;
- requirements by regulatory authorities to place additional warnings on the label of such products;
- requirement by regulatory authorities to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- potential lawsuits, which may result in us being held liable for harm caused to patients; and
- reputational harm.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- our collaboration with twoXAR, which relies upon artificial intelligence technology to generate potential product opportunities, may not generate viable product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may not be successful in meeting our diligence obligations under our existing collaboration with twoXAR or under future license agreements necessary to maintain and continue to use product candidate licenses in effect. In addition, if required in order to commercialize our product candidates, we may be unsuccessful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We may seek to obtain rights to intellectual property, through licenses from third parties and under patents that we do not own, to develop and commercialize additional product candidates, such as our collaboration with twoXAR. Because our programs may require the collaboration with or use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to maintain in effect these collaborations and proprietary rights. For example, we have certain specified diligence obligations under our collaboration with twoXAR. We may not be able to achieve the required diligence milestones in a timely manner, which may result in a right of termination by twoXAR, and we may be unable to successfully negotiate an extension or waiver of those termination rights. Any termination of the collaboration with twoXAR or future license agreements with third parties with respect to our product candidates would be expected to negatively impact our business prospects.

We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to license or acquire third-party intellectual property rights that are necessary for our product candidates, there can be no assurance that they will be available on favorable terms.

We collaborate with U.S. and foreign academic institutions to identify product candidates, accelerate our research and conduct development. Typically, these institutions have provided us with an option to negotiate an exclusive license to any of the institution's rights in the patents or other intellectual property resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue a program of interest to us.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third party, and our business and financial condition could suffer.

Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements

If our product candidates are approved, they will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or marketing authorization application, or MAA.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and operating results would be adversely affected.

We rely on third parties to conduct our clinical trials, and perform other clinical development-related services, such as drug shipping, blinding and randomization, data collection, and biostatistical analysis. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct, monitor and manage our ongoing clinical program. We rely on these parties for execution of clinical trials and we manage and control only certain aspects of their activities. We remain responsible for ensuring that each of our clinical trials 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 and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results 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. We cannot guarantee that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that activities conducted by our third-party vendors in support of any of our clinical trials comply with applicable requirements. Failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated and we may not be able to meet our current plans with respect to our product candidates. CRO contracts may also involve higher costs than anticipated, which could negatively affect our financial condition and operations.

We rely and expect to continue to rely on third parties to manufacture our clinical product supplies, and if approved, we intend to rely on third parties to produce and process our product candidates. Our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on outside vendors to manufacture clinical supplies of our product candidates and plan to continue relying on third parties to manufacture our product candidates on a commercial scale, if approved. We plan to rely on third-party manufacturers and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. There are expected to be a limited number of suppliers for the materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the study, any significant delay or discontinuity in the supply of a product candidate, or the active ingredient or other material components in the manufacture of the product candidate could delay completion of our clinical trials and result in potential delay in regulatory approval of our product candidates, which would harm our business and results of operations.

We do not have long-term supply agreements or commitments from those parties to supply our materials. Moreover, even if we had a longer-term supply arrangement, we may be precluded from entering into a back-up or alternative supplier arrangement which may increase the risk for further development, regulatory approval, or commercialization of our product candidates. We may also receive supply of drug substance or drug product that is deficient in quality or otherwise does not meet the specifications required to be used in clinical trials. In the past, we have experienced such deficiencies and have been required to seek alternative sources to meet our needs. We have not established clinical trial material supply agreements for AYX2 and may not be able to do so.

Certain components used in the manufacture of brivoligide are sourced from a single vendor.

Brivoligide is an oligonucleotide, and there are currently a limited number of oligonucleotide manufacturers with commercial sale capabilities globally. We currently use Nitto-Denko Avecia, Inc., or Avecia, as a single supplier for the brivoligide drug substance and do not have a long-term supply agreement or commitment from Avecia to supply our drug substance. If Avecia is unable or unwilling to meet our current or future needs for our drug substance on acceptable terms, or at all, we may be unable to locate alternative suppliers or manufacturers. While we intend to develop secondary sources for manufacturing of our drug candidates in the future, we may not be able to do so on commercially reasonable terms or at all. Any interruption in the supply of a key material could significantly delay our research and development process or increase our expenses for development and commercialization of our product candidates. Any interruption in supply of our product candidates from Avecia could result in delay of our clinical trials or interrupt our commercial supply, which would harm our business and results of operations.

We face intense competition from other companies developing products for the reduction of postoperative pain.

Brivoligide faces significant competition. If we are able to successfully develop brivoligide for the reduction of postoperative pain, it would compete with EXPAREL (bupivacaine liposome injectable suspension, marketed by Pacira Pharmaceuticals, Inc.), HTX-011 (bupivacaine and meloxicam, in development by Heron Therapeutics, NDA submitted to the FDA in 2019), Ofirmev (intravenous acetaminophen, marketed by Mallinckrodt Pharmaceuticals), branded and generic oral opioid pain therapeutics, branded and generic oral nonsteroidal anti-inflammatory drugs, or NSAIDs, and potentially other products in development for the reduction of postoperative pain that reach the market.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do, and have significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of 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 smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Small or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established pharmaceutical companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring or in-licensing technologies and products complementary to our programs or potentially advantageous to our business. If any of our competitors succeed in obtaining approval from the FDA or other regulatory authorities for their products sooner than we do or for products that are more effective or less costly than our products, our commercial opportunity could be significantly reduced. Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of new mechanisms of action, technologically improved or different products or drug delivery technologies may make our product candidates or platform technologies obsolete or noncompetitive.

We currently have no marketing and sales experience or capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We have no experience selling and marketing our product candidates and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

Further, given our lack of prior experience in marketing and selling pharmaceutical products, we may rely on future collaborators to commercialize our products. If collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, in particular in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

In addition to extensive internal efforts, the successful commercialization of brivoligide will require many third parties, over whom we have no control, to choose to utilize brivoligide. These third parties include physicians and hospital pharmacy and therapeutics committees, or P&T committees.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as our and what reimbursement codes our products may receive.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products.

Physicians must prescribe brivoligide for our commercialization to be successful. Because administration of brivoligide will be intended for patients scoring ≥16 on the PCS, and will require administration of the one-page PCS evaluation tool prior to surgery, physicians may not accept brivoligide as a viable addition to their patient treatment pathway.

If brivoligide does not achieve broad market acceptance, the revenues that are generated from our sales will be limited.

Risks Related to our Business Operations

Our future success depends in part on our ability to retain our President and Chief Executive Officer, Chief Medical Officer, and Chief Scientific Officer, and to attract, retain, and motivate other qualified personnel.

We are highly dependent upon the efforts of our senior management, including Rick Orr, our President and Chief Executive Officer, Donald C. Manning, our Chief Medical Officer, and Julien Mamet, our founder and Chief Scientific Officer. The loss of the services provided by these individuals may adversely impact the achievement of our objectives. These individuals could leave our employment at any time, as they are "at will" employees. The loss of the services of these individuals and other members of our senior management could delay or prevent the achievement of research, development, marketing, or product commercialization objectives. We do not maintain any "key-man" insurance policies on any of the key employees nor do we intend to obtain such insurance coverage. Recruiting and retaining other qualified employees, consultants, and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of key members of senior management could impede the progress of our research, development, and commercialization objectives.

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

As of September 30, 2019, we had six full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal, and other resources. Our management may need to divert a disproportionate amount of their 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 our infrastructure, 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 additional product candidates. If our management is unable to effectively manage growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot provide any assurance that, following any such acquisition, we will achieve the synergies expected in order to justify the transaction, which could result in a material adverse effect on our business and prospects.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may have a significant adverse effect on our business and results of operations.

There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate postapproval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (1) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (which through subsequent legislative amendments, was increased to 70% from 50% starting in 2019) off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (6) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (8) created a licensure framework for follow-on biologic products; and (9) established a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations. Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Most recently, the Trump administration released a "Blueprint," or plan, to reduce the cost of drugs. The Trump administration's Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. At the state level, individual states in the United States are increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begins commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Health Care Reform Laws requires 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 applicable group purchasing organizations; 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 pharmaceutical 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; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities may involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of hazardous materials. In some cases, hazardous materials and various wastes resulting from their use may be stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of hazardous materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters is located in the San Francisco Bay Area which has in the past experienced severe earthquakes and other natural disasters. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations or those of our collaborators, and have a material adverse effect on our business, results of operations, financial condition, and prospects. If a natural disaster, terrorist attack, power outage, or other event occurred that prevented us from using or damaged critical elements of our business and operations (such as the manufacturing facilities of our third-party contract manufacturers) our business may be disrupted for a substantial period of time. We have limited or no disaster recovery and business continuity plans in place currently and our business would be impaired in the event of a serious disaster or similar event. We may incur substantial expenses to develop and implement any disaster recovery and business continuity plans, which could have a material adverse effect on our business.

The terms of our Loan Agreement with Oxford place restrictions on our operating and financial flexibility.

The Loan Agreement subjects us and our subsidiaries to various affirmative and restrictive covenants, including a covenant against the occurrence of a "change in control," financial reporting obligations, and certain limitations on the incurrence of indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), collateral, transactions with affiliates or mergers or acquisitions. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders.

Additionally, we may be required to repay the entire amount of outstanding indebtedness under the Loan Agreement in cash if we fail to stay in compliance with our covenants or suffer some other event of default under the Loan Agreement. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Oxford could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the loan for its benefit, which collateral includes all of our property, including our intellectual property. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

Substantially all of our assets are subject to a first-priority lien in favor of Oxford under the Loan Agreement. The foreclosure on such assets or exercise of other remedies available to Oxford under the Loan Agreement could substantially harm our business operations and financial condition.

Substantially all of our assets are subject to a first-priority lien in favor of Oxford under the Loan Agreement. There can be no assurance that we will remain in compliance with our obligations under the Loan Agreement, including making required payments and complying with affirmative and negative covenants. In the event of foreclosure or exercise of other remedies by Oxford under such agreement on the assets pledged to Oxford, our business operations and financial condition will be substantially harmed.

Risks Related to our Intellectual Property

We intend to rely on exclusivity from patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity, we may not be able to compete effectively in our markets.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process can be 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 position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain in flux. We own the rights to issued patents and to patent applications that cover our product candidates and their application. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. Further, third parties may challenge the validity of our issued patents, their enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. There is no assurance that all 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. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing intellectual property around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

We may not have sufficient patent term protections for our products to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, our products may be open to competition from generic medications. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the United States Patent and Trademark Office, or USPTO. For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution. Further, it is possible for a third party to challenge the validity of our issued patents via litigation and/or post-grant administrative proceedings at the USPTO, which if successful, could invalidate the issued patents and lead to earlier market entry and competition by others.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data, regulatory exclusivity terms associated with the products. With respect to our product candidates brivoligide and AYX2, a portion of the potential commercial opportunity will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our products for an extended period, which would negatively impact our business and results of operations. If we do not have sufficient patent terms or regulatory exclusivity to protect our products, our business and results of operations will be adversely affected.

Patent laws and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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 their protection. The laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States. Publications of discoveries in the 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. We therefore cannot be certain that we were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. The applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, 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 a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements can be duly enforced or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our product candidates. We have conducted freedom to operate analyses with respect to only certain of our product candidates, and have not requested independent formal written opinions, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these product candidates. We also cannot guarantee that any of our analyses are exhaustive, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patents in the future and claim that the use of our technologies infringes upon their patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidate's formulations, manufacturing process, methods of use, or of any molecules formed during their manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Intellectual property may be discovered in the future through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

We have received grant awards from NIDA/NIH and NINDS/NIH for the development of brivoligide in the mastectomy model of postoperative pain and the development of AYX2, respectively. Intellectual property may be generated through the use of this U.S. government funding and would therefore be subject to certain federal regulations. As a result, the U.S. government may in the future have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Our product candidates may be subject to generic competition.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's finding of safety and effectiveness of a previously approved drug. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Innovative small molecule drugs may be eligible for certain periods of regulatory exclusivity (e.g., five years for new chemical entities, three years for changes to an approved drug requiring a new clinical trial, seven years for orphan drugs), which preclude FDA approval (or in some circumstances, FDA filing and review of) an ANDA or 505(b)(2) NDA relying on the FDA's finding of safety and effectiveness for the innovative drug. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the final drug product, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic applicant that seeks to market its product before expiration of the patents must include in the ANDA or 505(b)(2) what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

If there are patents listed for our product candidates in the Orange Book, ANDAs and 505(b)(2) NDAs with respect to those product candidates would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or licenses. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could more immediately face generic competition and our sales would likely decline materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

All of our assets are subject to a first-priority lien in favor of Oxford under a security agreement entered into in connection with the Loan Agreement with Oxford. The foreclosure on such assets or exercise of other remedies available to Oxford under the Loan Agreement could materially adversely affect our business operations and future prospects.

All of the assets (including intellectual property) owned by us are subject to a first-priority lien in favor of Oxford under a security agreement entered into in connection with the Loan Agreement with Oxford. There can be no assurance that we will remain in compliance with our obligations under the Loan Agreement. In the event of foreclosure or exercise of other remedies by Oxford under such agreement on the assets (including such intellectual property) pledged to Oxford, our ability to use and develop our product candidates as well as our business operations and future prospects will be materially adversely affected.

Although we are not currently involved in any significant litigation, we may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our potential licensors. Although we are not currently involved in any litigation, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are a commonplace. Grounds for a validity challenge of a patent could be an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome of such interference proceeding could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

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 a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements and make every effort to ensure that our employees, consultants, and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, and we are not currently subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to our Corporate Governance

Our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action asserting a claim against us that is governed by the internal affairs doctrine; or, to the maximum extent permitted by law, any other claim or dispute. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our bylaws described in the preceding sentence. If a court were to find the choice of forum provisions contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a significant impact on our business, financial condition and results of operations.

This exclusive forum provision will not apply to claims which are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, jurisdiction over which is exclusively vested by statute in the U.S. federal courts. As a result, this may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons.

Some provisions of our charter document and Delaware law may have antitakeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by the our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws as well as provisions of the DGCL, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- allowing the authorized number of our directors to be changed only by resolution of the board of directors;
- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of our board of directors, which will be responsible for appointing the members of our management. In addition, we will be subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

We are not subject to compliance with rules requiring the adoption of certain corporate governance measures and as a result our stockholders may have limited protections.

Each of the New York Stock Exchange and the Nasdaq Stock Market LLC require the implementation of various measures relating to corporate governance for listed companies. These measures are designed to enhance the integrity of corporate management and the securities markets and apply to securities which are listed on those stock exchanges. While we have adopted these measures, we will not be required to comply with many of the corporate governance provisions in the future for so long as our common stock is not listed on a national securities exchange. As a result, if we elect to cease compliance with any such measures, our stockholders may lose protections afforded to listed companies.

Risks Related to Ownership of our Common Stock

Private Adynxx has a material weakness in its internal control over financial reporting. If this material weakness persists or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report its financial results could be adversely affected.

Prior to the closing of the Merger, Adynxx was a private company and had limited accounting and financial reporting personnel and other resources with which to address its internal control over financial reporting. In connection with the audit of Private Adynxx's financial statements for the year ended December 31, 2018 and preparation of interim financial statements for the first three quarters of 2019, Private Adynxx and its independent registered public accounting firm identified a material weakness in Private Adynxx's internal controls over financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented or detected and corrected on a timely basis.

The material weakness related to Private Adynxx's inability to prepare accurate financial statements, resulting from a lack of adequate accounting personnel to timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with GAAP, including the recording of convertible note and related disclosures. In response to the material weakness, Adynxx is currently working to remediate the material weakness by retaining third-party consultants to help enhance its internal controls over financial reporting. There can be no assurance that these efforts will remediate the material weakness or avoid future weaknesses or deficiencies. Any failure to remediate the material weakness and any future weaknesses or deficiencies or any failure to implement required new or improved controls or difficulties encountered in their implementation could cause Adynxx to fail to meet its reporting obligations or result in material misstatements in its financial statements. Adynxx's management will be required to assess the effectiveness of its disclosure controls and procedures and internal control over financial reporting. If Adynxx is unable to remediate its material weakness, Adynxx's management may not be able to conclude that its disclosure controls and procedures or internal control over financial reporting are effective, which could result in investors losing confidence in its reported financial information and may lead to a decline in the stock price. Failure to comply with Section 404 of Sarbanes-Oxley could potentially subject Adynxx to sanctions or investigations by the SEC, the Financial Industry Regulatory Authority or other regulatory authorities, as well as increasing the risk of liability arising from litigation based on securities law.

The restatement of certain of our previously issued financial statements may lead to additional risks and uncertainties, including regulatory, stockholder or other actions, loss of investor and counterparty confidence and negative impacts on our stock price.

In November 2019, our management and audit committee concluded that our previously issued consolidated statements of operations for the three and six months ended June 30, 2019 and 2018 should not be relied upon and should be restated. We also discussed this assessment with our independent registered public accounting firm. The conclusion resulted from the determination that we incorrectly overstated the weighted average number of shares outstanding as of June 30, 2019 and 2018 by including the mandatory conversion of preferred stock into common stock upon completion of our reverse merger with Alliqua BioMedical, Inc. retroactively instead of prospectively. As a result, we understated the amounts of net loss per diluted share for the three and six months ended June 30, 2019 and 2018.

As a result of the restatement and associated non-reliance on our previously issued consolidated statements of operations for the three and six months ended June 30, 2019 and 2018, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the restatement. In addition, the attention of our management team has been diverted by these efforts. We could also be subject to regulatory, stockholder or other actions in connection with the restatement, which would, regardless of the outcome, consume management's time and attention and may result in additional legal, accounting, and other costs. If we do not prevail in any such proceedings, we could be required to pay damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our stockholders or counterparties to lose confidence in us. Further, in connection with the restatement, our management may identify additional material weaknesses in our internal control over financial reporting. Any failure of our internal controls could also negatively impact the results of periodic management evaluations required under Section 404 of the Sarbanes-Oxley Act. Our management has previously concluded, including as a result of the restatement, that our disclosure controls and procedures as of June 30, 2019 are not effective at a level that provides reasonable assurance, and may make similar conclusions for future periods. Any of these occurrences could harm our business, results of operations, financial condition, and stock price.

Our stock price may be volatile and may decline regardless of our operating performance

Our stock price has been and is likely to continue to be volatile. The trading prices of the securities of companies in our industry have been highly volatile. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

- investors' general perception of our company and our business;
- recruitment or departure of key personnel;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the United States or foreign jurisdictions, or speculation regarding such changes;
- failure to comply with covenants and obligations under our debt instruments and agreements;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies in our industry. Stock prices of such companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies.

In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management, and harm our business.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon our common stock outstanding as of September 30, 2019, our executive officers, directors and current beneficial owners of 5% or more of our common stock, in the aggregate, beneficially own approximately 89.3% of our outstanding common stock. These stockholders, acting together, are able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting reporting companies in the United States, which may harm our business.

As a public company in the United States quoted on the OTCQB and subject to the reporting requirements of the Exchange Act, we will incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

The sale or availability for sale of a substantial number of shares of our common stock could negatively impact the market price of our shares.

Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, including by our directors, officers and significant stockholders following the expiration of lock-up arrangements entered into in connection with the Merger, could significantly reduce the market price of our common stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Additionally, sales of our common stock by our officers or directors, even when done during an open trading window under our policies with respect to insider sales may adversely impact the trading price of our common stock. Although we do not expect that the relatively small volume of such sales will itself significantly impact the trading price of our common stock, the market could react negatively to the announcement of such sales, which could in turn affect the trading price of our common stock.

Shares of our common stock are thinly traded and may continue to be thinly traded in the future.

Although a trading market for our common stock exists, the trading volume has not been significant, due in part to a substantial number of our outstanding shares being subject to contractual lock-up and other legal restrictions. There can be no assurance that an active trading market for our common stock will develop or, if developed, be sustained in the future, even following the lapse or expiration of such lock-up or other legal restrictions. As a result of the thin trading market or "float" for our stock, the market price for our common stock may fluctuate significantly more than the stock market as a whole. Without a large float, our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his or her investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price for our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future.

In addition, the price of our securities can vary due to general economic conditions and forecasts, our general business condition and the release of our financial reports. Additionally, because our securities are currently quoted on the OTC Markets, the liquidity and price of our securities may be substantially more limited than if we were quoted or listed on another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained. In the absence of an active trading market for our common stock, stockholders may not be able to sell their common stock at or above the price at which they acquired the shares or at the time that they would like to sell. We cannot predict the prices at which our common stock will trade. We do not intend to apply to list the common stock on any securities exchange or nationally recognized trading system in connection with the offering. In addition, we cannot assure you that we will be able to meet the initial listing standards of any national securities exchange, or, if we do meet such initial qualitative listing standards, that we will be able to maintain any such listing.

If securities or industry analysts do not publish research or reports about our business, or if they downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We are not currently covered by any securities or industry analysts. If no analysts elect to cover us in the future, or if one or more of the analysts who may cover us in the future downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. Further, we do not have any control over these analysts. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. 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.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 95,000,000 shares of common stock and up to 1,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. For example, we have issued from time to time Notes to certain of our significant shareholders that will convert into shares of our common stock upon, among other things, the occurrence of a qualified financing. We have also previously issued and currently have outstanding warrants to purchase shares of our common stock. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Our common stock is subject to the "penny stock" rules of the SEC and the trading market in the securities is limited, which makes transactions in the stock cumbersome and may reduce the value of an investment in the stock.

Rule 15g-9 under the Exchange Act establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (a) that a broker or dealer approve a person's account for transactions in penny stocks; and (b) the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must: (a) obtain financial information and investment experience objectives of the person and (b) make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form: (a) sets forth the basis on which the broker or dealer made the suitability determination; and (b) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our common stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker or dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

If we fail to remain current in our reporting requirements, we could lose certain privileges on the OTCQB which would impact the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

As a company traded on the OTCQB, we must be current with our filings pursuant to Sections 13 and 15(d) of the Exchange Act in order to maintain price quotation privileges on the OTCQB. If we fail to remain current in our reporting requirements, the market liquidity of our securities could be harmed by impacting the ability of broker-dealers to trade our securities and the ability of stockholders to sell their securities in the secondary market.

Our ability to use net operating losses to offset future taxable income may be subject to limitation.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the tax act informally known as the 2017 Tax Cuts and Jobs Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the 2017 Tax Cuts and Jobs Act. As of December 31, 2018, we had federal net operating loss carry forwards of approximately $33.5 million. The net operating loss of $28.7 million, carried forward from tax years ended before January 1, 2018, will begin to expire in 2033. Net operating losses incurred after December 31, 2017, which currently amounts to $4.8 million, may be carried forward indefinitely and will not expire. As of January 1, 2019, we had federal and California research and development tax credit carry forwards of approximately $1.8 million and $0.7 million, respectively. The federal research and development tax credit carry forwards will begin to expire in 2031 and the California research and development tax credit carry forwards are available indefinitely until utilized.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or, the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating losses and net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. It is possible that we have in the past undergone, and in the future may undergo, an ownership change, which could result in additional limitations on our use of net operating loss carryforwards and certain other tax attributes. This could have a material adverse effect on cash flow and results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Sales of Unregistered Securities

From July to September 2019, we issued and sold convertible promissory notes in the aggregate principal amount of $0.85 million to two accredited investors.

For a description of the terms of conversion of the convertible notes, see *'Note 7 -Term Loans and Convertible Promissory Notes'* in Part I, Item 1 (Financial Statements) to this Quarterly Report on Form 10-Q.

Use of Proceeds from Registered Securities

None.

Repurchase of Shares of Company Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 2. MINE SAFETY DISCLOSURES

None.

ITEM 2. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Index	Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Certificate of Incorporation of Alliqua BioMedical, Inc.	8-K	001-36278	3.1	June 11, 2014
3.2	Certificate of Amendment to the Certificate of Incorporation dated June 5, 2014	8-K	001-36278	3.3	June 11, 2014
3.3	Certificate of Amendment to the Certificate of Incorporation dated May 6, 2016	8-K	001-36278	3.1	May 6, 2016
3.4	Certificate of Amendment to the Certificate of Incorporation dated October 5, 2017	8-K	001-36278	3.1	October 5, 2017
3.5	Certificate of Amendment to the Certificate of Incorporation dated May 3, 2019	8-K	001-36278	3.1	May 9, 2019
3.6	Certificate of Amendment to the Certificate of Incorporation dated May 3, 2019	8-K	001-36278	3.2	May 9, 2019
3.7	Bylaws	8-K	001-36278	3.2	June 11, 2014
31	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith).				
32†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).				
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.				

† In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control over Financial Reporting and Certification of Disclosure in Exchange Act; this exhibit is furnished with this Quarterly Report on Form 10-Q and is not deemed "filed" with the Securities and Exchange Commission and is not incorporated by reference in any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filings.

Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of the Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

ADYNXX, INC.

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.

ADYNXX, INC.

Dated: November 14, 2019

By: /s/ RICK ORR
Rick Orr
President and Chief Executive Officer
(*Principal Executive Officer and Principal Financial Officer*)

Dated: November 14, 2019

By: /s/ DINA GONZALEZ
Dina Gonzalez
Controller
(*Principal Accounting Officer*)

Exhibit 31

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick Orr, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Adynxx, 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) I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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) I have disclosed, based on my 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 14, 2019

/s/ Rick Orr
Rick Orr
President and Chief Executive Officer
(*principal executive officer and principal financial officer*)

Exhibit 32

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick Orr, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Quarterly Report on Form 10-Q of Adynxx, Inc. for the quarter ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects, the financial condition and results of operations of Adynxx, Inc.

Date: November 14, 2019

/s/ Rick Orr
Rick Orr
President and Chief Executive Officer
(principal executive officer and principal financial officer)

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to Adynxx, Inc. and will be retained by Adynxx, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.