XBiotech Inc.
Form 10-Q
October 31, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**For the quarterly period ended September 30, 2018**

**or**

**Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Commission File Number 001-37437**

**XBIOTECH INC.**

**(Exact name of registrant as specified in charter)**

| | |
|---|---|
| **British Columbia, Canada** | — |
| (State or other jurisdiction of incorporation or organization) | **(IRS Employer Identification No.)** |

**5217 Winnebago Ln, Austin, TX 78744**

**(Address of principal executive offices)(Zip Code)**

**Telephone Number (512) 386-2900**

**(Registrant's telephone number, including Area Code)**

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

1

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

| | |
|---|---|
| Large accelerated filer | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| | Emerging growth company |

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

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

As of October 31, 2018, there were 35,819,772 shares of the Registrant's common stock issued and outstanding.

**XBIOTECH INC.**

**THREE MONTHS ENDED SEPTERMBER 30, 2018**

**INDEX**

**CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. You can identify forward-looking statements by terminology such as “may,” “will,” “should,” “would,” “could,” “expects,” “plans,” “contempla “anticipates,” “believes,” “estimates,” “predicts,” “projects,” “intend” or “continue” or the negative of such terms or other com terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These forward-looking statements include, but are not limited to statements about:

- our ability to obtain regulatory approval to market and sell Xilonix™ in the United States, Europe and elsewhere;
- the initiation, timing, cost, progress and success of our research and development programs, preclinical studies and clinical trials for Xilonix™ and other product candidates;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to successfully commercialize the sale of Xilonix™ in the United States, Europe and elsewhere;
- our ability to recruit sufficient numbers of patients for our future clinical trials for our pharmaceutical products;
- our ability to achieve profitability;
- our ability to obtain funding for our operations, including research funding;
- our ability to identify additional new products using our True Human™ antibody discovery platform;
- the implementation of our business model and strategic plans;
- our ability to develop and commercialize product candidates for orphan and niche indications independently;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;
- the rate and degree of market acceptance and clinical utility of Xilonix™ and future products, if any;
- the timing of and our collaborators’ ability to obtain and maintain regulatory approvals for our product candidates;

- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our belief in the sufficiency of our cash flows to meet our needs for at least the next 12 to 24 months;

- our expectations regarding the timing during which we will be an emerging growth company under the JOBS Act;
- our ability to engage and retain the employees required to grow our business;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

All forward looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those under the heading "Risk Factors" included in our annual report for the year ended December 31, 2017 filed with the SEC on March 16, 2018, and elsewhere in this Quarterly Report on Form 10-Q. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain medical conditions, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

**XBiotech Inc.**

Consolidated Balance Sheets

(in thousands, except share data)

| | September 30, 2018 (unaudited) | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 20,849 | $ 31,768 |
| Prepaid expenses and other current assets | 457 | 1,564 |
| Total current assets | 21,306 | 33,332 |
| Property and equipment, net | 27,938 | 29,640 |
| Total assets | $ 49,244 | $ 62,972 |
| | | |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $ 878 | $ 1,730 |
| Accrued expenses | 1,422 | 1,062 |
| Total current liabilities | 2,300 | 2,792 |
| Long-term liabilities: | | |
| Deferred rent | 7 | 18 |
| Total liabilities | 2,307 | 2,810 |
| | | |
| Shareholders' equity: | | |
| Preferred stock, no par value, unlimited shares authorized, no shares outstanding | - | - |
| Common stock, no par value, unlimited shares authorized, 35,819,772 and 35,439,272 shares outstanding at September 30, 2018 and December 31, 2017, respectively | 278,879 | 277,492 |
| Accumulated other comprehensive loss | (353) | (768) |
| Accumulated deficit | (231,589) | (216,562) |
| Total shareholders' equity | 46,937 | 60,162 |
| | | |
| Total liabilities and shareholders' equity | $ 49,244 | $ 62,972 |

*See accompanying notes.*

**XBiotech Inc.**

Consolidated Statements of Operations

(in thousands, except share and per share data)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 (unaudited) | 2017 (unaudited) | 2018 (unaudited) | 2017 (unaudited) |
| Operating expenses: | | | | |
| Research and development | $3,940 | $4,930 | $10,882 | $20,518 |
| General and administrative | 1,175 | 1,663 | 4,004 | 6,035 |
| Total operating expenses | 5,115 | 6,593 | 14,886 | 26,553 |
| Loss from operations | (5,115) | (6,593) | (14,886) | (26,553) |
| Other income (loss): | | | | |
| Interest income | 100 | 123 | 270 | 287 |
| Foreign exchange gain (loss) | (36) | 265 | (411) | 365 |
| Total other income (loss) | 64 | 388 | (141) | 652 |
| Net loss | $(5,051) | $(6,205) | $(15,027) | $(25,901) |
| Net loss per share—basic and diluted | $(0.14) | $(0.18) | $(0.42) | $(0.72) |
| Shares used to compute basic and diluted net loss per share | 35,819,772 | 35,423,105 | 35,795,881 | 35,732,564 |

*See accompanying notes.*

**XBiotech Inc.**

Consolidated Statements of Comprehensive Loss

(in thousands)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 (unaudited) | 2017 (unaudited) | 2018 (unaudited) | 2017 (unaudited) |
| Net loss | $ (5,051) | $ (6,205) | $ (15,027) | $ (25,901) |
| Foreign currency translation adjustment | 28 | (290) | 415 | (673) |
| Comprehensive loss | $ (5,023) | $ (6,495) | $ (14,612) | $ (26,574) |

*See accompanying notes.*

**XBiotech Inc.**

Consolidated Statements of Cash Flows

(in thousands)

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 (unaudited) | 2017 (unaudited) |
| Operating activities | | |
| Net loss | $ (15,027) | $ (25,901) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 1,816 | 889 |
| Share-based compensation expense | 1,186 | 1,340 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 1,108 | 1,294 |
| Accounts payable | (853) | (2,207) |
| Accrued expenses | 360 | (2,254) |
| Deferred rent | (11) | (3) |
| Net cash used in operating activities | (11,421) | (26,842) |
| | | |
| Investing activities | | |
| Purchase of property and equipment | (114) | (1,151) |
| Net cash used in investing activities | (114) | (1,151) |
| | | |
| Financing activities | | |
| Issuance of common stock and warrants, net | - | 32,620 |
| Issuance of common stock under stock option plan | 201 | 699 |
| Net cash provided by financing activities | 201 | 33,319 |
| Effect of foreign exchange rate on cash and cash equivalents | 415 | (673) |
| | | |
| Net change in cash and cash equivalents | (10,919) | 4,653 |
| Cash and cash equivalents, beginning of period | 31,768 | 34,324 |
| Cash and cash equivalents, end of period | $ 20,849 | $ 38,977 |

*See accompanying notes.*

**XBiotech Inc.**

Notes to Consolidated Financial Statements (Unaudited)

## 1. Organization

XBiotech Inc. ("XBiotech" or "the Company") was incorporated in Canada on March 22, 2005. XBiotech USA, Inc., a wholly-owned subsidiary of the Company, was incorporated in Delaware, United States ("U.S.") in November 2007. XBiotech Switzerland AG, a wholly-owned subsidiary of the Company, was incorporated in Zug, Switzerland in August 2010. XBiotech Japan K.K., a wholly-owned subsidiary of the Company, was incorporated in Tokyo, Japan in March 2013. XBiotech Germany GmbH, a wholly-owned subsidiary of the Company, was incorporated in Germany in January 2014. The Company's headquarters are located in Austin, Texas.

XBiotech Inc. is a pre-market biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization or otherwise engineered. The Company believes that naturally occurring monoclonal antibodies have the potential to be safer and more effective than their non-naturally occurring counterparts. XBiotech is focused on developing its True Human™ pipeline and manufacturing system. The Company's pipeline consists of product candidates at various stages of development across an array of indications including oncology, dermatology, other inflammatory conditions, such as peripheral vascular disease, type 2 diabetes, and infectious diseases.

## 2. Significant Accounting Policies

### Basis of Presentation

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("US GAAP"). In the opinion of management, the accompanying consolidated financial statements reflect all adjustments (consisting only of normal recurring items) considered necessary to present fairly the Company's financial position at September 30, 2018 and December 31, 2017, the results of its operations and comprehensive loss for the three month and nine month periods ended September 30, 2018 and 2017, and the cash flows for the nine month period ended September 30, 2018 and 2017.

### Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany transactions have been eliminated upon consolidation.

**Use of Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported values of amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

**Research and Development Costs**

All research and development costs are charged to expense as incurred. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract clinical trial research services, the costs of laboratory consumables, equipment and facilities, license fees and other external costs. Costs incurred to acquire licenses for intellectual property to be used in research and development activities with no alternative future use are expensed as incurred as research and development costs.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

**Share-Based Compensation**

The Company accounts for its share-based compensation awards in accordance with ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. To determine the fair value of its common stock, the Company uses the closing price of the Company's common stock as reported by NASDAQ. For awards subject to service-based vesting conditions, the Company recognizes share-based compensation expense, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur rather than on an estimated basis.

Share-based compensation expense recognized for the three and nine months ended September 30, 2018 and 2017 was included in the following line items on the Consolidated Statements of Operations (in thousands).

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | $ 224 | $ 217 | $474 | $237 |
| General and administrative | 215 | 228 | $712 | 1,828 |
| Total share-based compensation expense | $ 439 | $ 445 | $1,186 | $2,065 |

The fair value of each option is estimated on the date of grant using the Black-Scholes method with the following assumptions:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Dividend yield | - | - | - | - |
| Expected volatility | 79% - 80% | 67% | 67% - 80% | 65% - 67% |
| Risk-free interest rate | 2.79% - 2.99% | 1.90% - 2.07% | 2.38% - 2.99% | 1.83% - 2.41% |
| Expected life (in years) | 6 - 6.25 | 5.75 - 6.25 | 5.38 - 10 | 5.38 - 10 |
| Weighted-average grant date fair value per share | 3.77 | $4.86 | 4.45 | $4.85 |

**Cash and Cash Equivalents**

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consisted primarily of cash on deposit in U.S., German, Swiss, Japanese and Canadian banks. Cash and cash equivalents are stated at cost which approximates fair value.

**Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents. The Company holds these investments in highly-rated financial institutions, and limits the amounts of credit exposure to any one financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

**Fair Value Measurements**

The Company follows ASC Topic 820, *Fair Value Measurements and Disclosures*, which establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between assumptions based on market date (observable inputs) and the Company's own assumptions (unobservable inputs). The hierarchy consists of three levels:

- Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.
- Level 3—Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

At September 30, 2018 and December 31, 2017, the Company did not have any assets or liabilities that are measured at fair value on a recurring basis. The carrying amounts reflected in the balance sheets for cash and cash equivalents, prepaid expenses and other current assets, accounts payable, and accrued expenses approximate their fair values at September 30, 2018 and December 31, 2017, due to their short-term nature.

**Property and Equipment**

Property and equipment, which consists of land, construction in process, furniture and fixtures, computers and office equipment, scientific equipment, leasehold improvements, vehicles and building are stated at cost and depreciated over the estimated useful lives of the assets, with the exception of land and construction in process which are not depreciated, using the straight line method. The useful lives are as follows:

- Furniture and fixtures 7 years
- Office equipment 5 years
- Leasehold improvements Shorter of asset's useful life or remaining lease term
- Scientific equipment 5 years
- Vehicles 5 years

• Building 39 years

Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized.

**Impairment of Long-Lived Assets**

The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment through September 30, 2018.

**Income Taxes**

The Company makes estimates and judgments in determining the need for a provision for income taxes, including the estimation of its taxable income or loss for the full fiscal year. The Company has accumulated significant deferred tax assets that reflect the tax effects of net operating losses and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. The Company is uncertain about the timing and amount of any future earnings. Accordingly, the Company offsets these deferred tax assets with a valuation allowance. The Company may in the future determine that certain deferred tax assets will likely be realized, in which case the Company will reduce its valuation allowance in the period in which such determination is made. If the valuation allowance is reduced, the Company may recognize a benefit from income taxes in its consolidated statements of operations in that period.

The GAAP guidance requires recognition of the impact of a tax position in our financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense. Determining the consolidated provision for income taxes involves judgments, estimates and the application of complex tax regulations. We are required to provide for income taxes in each of the jurisdictions where we operate, including estimated liabilities for uncertain tax positions. Although we believe that we have provided adequate liabilities for uncertain tax positions, the actual liability resulting from examinations by taxing authorities could differ from the recorded income tax liabilities and could result in additional income tax expense having a material impact on our consolidated results of operations. Changes of estimates in our income tax liabilities are reflected in our income tax provision in the period in which the factors resulting in the change to our estimate become known to us. We benefit from the tax credit incentives under the U.S. research and experimentation tax credit extended to taxpayers engaged in qualified research and experimental activities while carrying on a trade or business.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act, or TCJA, tax reform legislation. The TCJA makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The TCJA reduced the U.S. corporate tax rate from the current rate of 34 percent down to 21 percent starting on January 1, 2018. As a result of the TCJA, the Company was required to revalue deferred tax assets and liabilities at 21 percent. As of and for the year ended December 31, 2017, this revaluation resulted in a provision of $4.5 million to income tax expense in continuing operations and a corresponding reduction in the valuation allowance. As a result, there was no impact to the Company’s consolidated statements of comprehensive loss as a result of the reduction in tax rates.

As the Company does not have all of the necessary information to analyze all income tax effects of the TCJA, the Company will continue to make and refine calculations and estimates as additional information is obtained, which could potentially affect the provisional amounts relating to the deferred income taxes, including but not limited to

deferred tax assets related to share-based compensation expenses. Where the Company has not yet been able to make reasonable estimates of the impact of certain elements, the Company has not recorded any amounts related to those elements and has continued accounting for them in accordance with ASC 740 on the basis of the tax laws in effect immediately prior to the enactment of the TCJA. The Company expects to complete a detailed analysis no later than the fourth quarter of 2018.

**Foreign Currency Transactions**

Certain transactions are denominated in a currency other than the Company's functional currency of the U.S. dollar, and the Company generates assets and liabilities that are fixed in terms of the amount of foreign currency that will be received or paid. At each balance sheet date, the Company adjusts the assets and liabilities to reflect the current exchange rate, resulting in a translation gain or loss. Transaction gains and losses are also realized upon a settlement of a foreign currency transaction in determining net loss for the period in which the transaction is settled.

**Comprehensive Income (Loss)**

ASC Topic 220, *Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments.

**Segment and Geographic Information**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the Chief Executive Officer. The Company and the chief operating decision maker view the Company's operations and manage its business as one operating segment. Substantially all of the Company's operations are in the U.S. geographic segment.

**Net Loss Per Share**

Net loss per share ("EPS") is computed by dividing net loss by the weighted average number of common shares outstanding during each period. Diluted EPS is computed by dividing net loss by the weighted average number of common shares and common share equivalents outstanding (if dilutive) during each period. The number of common share equivalents, which include stock options, is computed using the treasury stock method.

**Subsequent Events**

The Company considered events or transactions occurring after the balance sheet date but prior to the date the consolidated financial statements are available to be issued for potential recognition or disclosure in its consolidated financial statements. The Company has evaluated subsequent events through the date of filing this Form 10-Q.

**Recent Accounting Pronouncements**

*Recently Issued Accounting Pronouncements*

In February 2016, the FASB issued final guidance that will change the accounting for leases, Accounting Standards Update (ASU) No. 2016-02, “Leases.” The FASB issued final guidance that requires lessees to put most leases on their balance sheets but recognize expenses on their income statements in a manner similar to today’s accounting. The guidance also eliminates today’s real estate-specific provisions for all entities. The pronouncement will also require additional disclosures about the amount, timing and uncertainty of cash flows arising from leases. For calendar-year public business entities and certain calendar-year not-for-profit entities and employee benefit plans, the guidance is effective in 2019, and interim periods within that year, and early adoption is permitted. We anticipate that we will adopt ASU No. 2016-02 for our fiscal year commencing on January 1, 2019. We expect to apply the modified retrospective approach and we are currently in the process of analyzing our leases. The adoption of this standard will require the Company to record its operating leases on the balance sheet. The Company is currently evaluating the impact of this pronouncement on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, to provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in accordance with ASC No. 718, Compensation - Stock Compensation. We adopted ASC No. 2017-09 for our fiscal year commencing on January 1, 2018. This guidance is to be applied prospectively to an award modified on or after the adoption date. The adoption of this accounting policy did not have a material impact on the Company’s financial statements.

**3. Property and Equipment**

Property and equipment were comprised of the following (in thousands):

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Manufacturing equipment | $ 5,319 | $ 6,058 |
| Winnebago building | 20,080 | 20,484 |
| Other fixed assets | 2,539 | 3,098 |
| Total property and equipment | $ 27,938 | $ 29,640 |

**4. Common Stock**

Pursuant to its Articles, the Company has an unlimited number of shares available for issuance with no par value.

14

From January through December 2016, 204 thousand shares of common stock were issued upon the exercise of stock options at a price of $0.74 to $19.09 per share for total proceeds of $1.1 million.

From November through December 2016, under the Common Stock Sales Agreement with H.C. Wainwright & Co. LLC, the Company sold 145 thousand shares of common stock at a price between $13.60 to $14.17 per share for total proceeds of $1.8 million.

In February 2017, under the Common Stock Sales Agreement with H.C. Wainwright & Co. LLC, the Company sold 87 thousand shares of common stock at a price between $12.09 to $12.37 per share for total proceeds of $1.0 million.

In March 2017, the Company sold 2.4 million shares of common stock at a net price of $13.00 for total proceeds of approximately $31.6 million from investors.

From January through December 2017, 290 thousand shares of common stock were issued upon the exercise of stock options at a price of $2.50 to $14.71 per share for a total of $703 thousand.

From January through March 2018, 81 thousand shares of common stock were issued upon the exercise of stock options at a price of $2.50 per share for total proceeds of $201 thousand.

**5. Common Stock Options**

On November 11, 2005 and April 1, 2015, the board of directors of the Company adopted stock option plans (“the Plans”) pursuant to which the Company may grant incentive stock options to directors, officers, employees or consultants of the Company or an affiliate or other persons as the Compensation Committee may approve.

All options will be non-transferable and may be exercised only by the participant, or in the event of the death of the participant, a legal representative until the earlier of the options’ expiry date or the first anniversary of the participant’s death, or such other date as may be specified by the Compensation Committee.

The term of the options is at the discretion of the Compensation Committee, but may not exceed 10 years from the grant date. The options expire on the earlier of the expiration date or the date three months following the day on which the participant ceases to be an officer or employee of or consultant to the Company, or in the event of the termination of the participant with cause, the date of such termination. Options held by non-employee Directors have an exercise period coterminous with the term of the options.

The number of common shares reserved for issuance to any one person pursuant to the Plans shall not, in aggregate, exceed 5% of the total number of outstanding common shares. The exercise price per common share under each option will be the fair market value of such shares at the time of the grant. Upon stock option exercise, the Company issues new shares of common stock.

A summary of changes in common stock options issued under the Plans is as follows:

| | Options | Exercise Price | Weighted-Average Exercise Price |
|---|---|---|---|
| Options outstanding at December 31, 2017 | 5,303,624 | $2.5 - $21.99 | 7.69 |
| Granted | 926,500 | 2.71 - 5.13 | 4.37 |
| Exercised | (80,500) | 2.5 | 2.50 |
| Forfeitures | (699,935) | 2.50 - 19.09 | 6.20 |
| Options outstanding at September 30, 2018 | 5,449,689 | $2.5 - $21.99 | 4.88 |

As of September 30, 2018, there was approximately $3.0 million of unrecognized compensation cost, related to stock options granted under the Plans which will be amortized to stock compensation expense over the next 2.2 years.

**6. Commitments and Contingencies**

On January 12, 2008, the Company entered a lease agreement to lease a facility in Austin, Texas, U.S. On September 15, 2010, the Company entered into a second lease agreement to lease additional space in Austin, Texas, U.S. On March 20, 2013, the company extended the lease for another 21 months with the same terms and rental rates as the current leases. On February 28, 2015, the Company extended the leases for another four years with two years early termination right. The future minimum lease payments are as follows as of September 30, 2018 (in thousands):

| | |
|---|---|
| 2018 | $118 |
| 2019 | $79 |

Rent expense for the three months and nine months ended September 30, 2018 were $197 thousand and $590 thousand, respectively, compared to $186 thousand and $558 thousand for the three months and nine months ended September 30, 2017, respectively.

On October 23, 2018, the honorable Judge Dustin M. Howell of the 459th Travis County District Court has issued a letter ruling granting the Company’s Motion to Dismiss the securities class action complaint brought against XBiotech (Case D-1-GN-17-003063). The District Court has directed the parties to prepare a formal order memorializing the ruling. Two federal cases were previously filed in the U.S. District Court for the Western District of Texas, but both of those cases have also been dismissed. Therefore, there no longer remains any litigation involving the Company.

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

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

**Overview**

XBiotech Inc. ("XBiotech" or "the Company") is a pre-market biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization or otherwise engineered. We believe that naturally occurring monoclonal antibodies have the potential to be safer and more effective than their non-naturally occurring counterparts. XBiotech is focused on developing its True Human™ pipeline and manufacturing system.

We have never been profitable and, as of September 30, 2018, we had an accumulated deficit of $231.6 million. We had net losses of $5.1 million and $15.0 million for the three months and nine months ended September 30, 2018, respectively, compared to $6.2 million and $25.9 million for the three months and nine months ended September 30, 2017, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical testing and clinical trials and seek regulatory approval and eventual commercialization. In addition to these increasing research and development expenses, we expect general and administrative costs to increase as we add personnel and continue to operate as a public company. We will need to generate significant revenues to achieve profitability, and we may never do so. As of September 30, 2018, we had 48 employees.

**Recent Events:**

***Clinical Programs***

**Atopic Dermatitis**

In April 2018, XBiotech announced the launch of a Phase 2, open label clinical trial to evaluate the Company's True Human™ monoclonal antibody, bermekimab, in patients with moderate to severe Atopic Dermatitis (AD). This ongoing study is evaluating the safety and efficacy of bermekimab in AD patients after relatively short durations of weekly treatment compared to the currently approved antibody therapy (4 and 8 weeks compared to 16 weeks, respectively).

The study utilizes the Company's new pre-filled syringes to deliver bermekimab therapy via subcutaneous injection. During Q3, we announced successful completion and positive interim findings for the first cohort of this study, which involved nine patients who received a low dose (200mg/weekly) and four weekly treatments with bermekimab. The Company reported that the 200mg subcutaneous injections were well-tolerated and that bermekimab treatment was associated with statistically significant improvement in several endpoints assessing efficacy. Enrollment was completed during Q3, totaling 37 patients, with 28 patients in the second, higher-dose cohort. Completion of the study and results analysis is expected around year end 2018 or early 2019.

**Hidradenitis Suppurativa**

During Q3, XBiotech announced enrollment of the first patient in its Phase 2, open label clinical study to evaluate bermekimab in patients with moderate to severe Hidradenitis Suppurativa (HS). U.S. recruitment in this study was completed in Q3 with enrollment rates exceeding expectations. The very robust enrollment is viewed by the Company as evidencing the strong desire for new treatment options in HS and the potential marketability for HS bermekimab therapy should it successfully advance through marketing approval. Importantly, the clinical study is evaluating bermekimab in patients that have failed anti-TNF therapy and in patients that have had no prior anti-TNF treatment history (the only approved biological drug to treat HS is the anti-TNF drug, Humira, which is projected to reach $21 billion in annual sales by 2020). HS patients are being treated with 13 weekly subcutaneous injections of bermekimab. It was previously demonstrated in the Company's double blind, placebo-controlled study of patients with HS that bermekimab, when administered as an intravenous therapy, was effective for treating HS patients who failed or were ineligible for anti-TNF therapy. The Company projects completion of the current study and a results read-out during the first quarter of 2019.

**Pancreatic Cancer**

XBiotech is evaluating bermekimab in combination with chemotherapy for the treatment of patients with pancreatic cancer. A clinical study headed by Dr. Andrew Hendifar, MD is being conducted at Cedars-Sinai Medical Center, Los Angeles, CA to examine the safety of bermekimab in combination with Onivyde (nanoliposomal irinotecan) and 5-fluorouracil (5FU)/folinic acid (leucovorin) for pancreatic cancer patients with wasting syndrome. Enrollment is expected to be completed around year end 2018. Bermekimab is believed to block tumor-related inflammation that is involved in neovascularization and tissue matrix remodeling, which is a crucial process for the growth and spread of tumors. As well, bermekimab may block tumor related inflammation that causes central nervous system (CNS) mediated metabolic dysregulation that can lead to wasting. The molecular target of bermekimab, IL-1 , may also be involved in tumor metastasis. In a Phase III randomized study in advanced cancer patients, patients that achieved the primary endpoint (as defined in Hickish et al., Lancet Oncology 2017) had lower incidence of disease progression. In another Phase III cancer study, bermekimab treatment was associated with a significant increase in lean body mass. Patients with pancreatic cancer often suffer from aggressive disease progression and wasting. The disease is known for its rapid mortality and high degree of morbidity. Bermekimab may also improve the anti-tumor activity of the cytotoxic chemotherapy and help patients endure longer exposure to these agents by reducing the inflammatory response caused by the treatment. Although the mechanism of cachexia in pancreatic cancer is not fully understood, bermekimab could help reduce this debilitating symptom by enabling patients to maintain and/or gain lean body mass during cancer treatment.

***Research & Development***

**Overview**

During Q3, XBiotech continued to consolidate operations at its Winnebago campus facility. All personnel and operations with the exception of in vivo research activities were successfully transferred and are now operating at the Winnebago campus. During Q3, the Company completed design and received city permits for constructing an annex building to house a new animal research facility at its Winnebago campus. This new facility will mark the final stage of the Company's move to consolidate operations and transfer its R&D group from the East Riverside Drive location to the Winnebago campus. XBiotech's new annex facility will include a state-of-the-art "biobubble" for working with infectious diseases, will house a Class II containment work space for pathogenic virus culture and propagation, and will include a lab for screening human blood donations and conducting the first stage of discovery work for identifying new antibody therapies. R&D activities in the new facility are planned to commence during Q1 2019.

**C. difficile**

XBiotech continues to make progress with its key pre-clinical R&D programs. In vivo testing of the *C. difficile* prophylaxis is ongoing. The Company's scientists have established what we believe is a more challenging model for the disease. The strain of *C. difficile* now being used in pre-clinical development work produces a more aggressive and lethal form of disease. We believe that the new model will better establish the potential for our True Human™ antibody to prevent or treat human infections with *C. difficile*.

**Influenza**

The Company continues to progress with developing its True Human™ antibodies for the treatment and prevention of influenza. XBiotech has focused on developing antibodies that target hemagglutinin and neuraminidase, two key surface moieties of the influenza virus. These key antibodies have been genetically introduced in cell lines to enable manufacturing production. A highly specific selection process has been ongoing during Q3 to identify True Human™ antibodies that target precise regions of the hemagglutinin. This process, which is expected to allow the antibody therapy to be effective in a broader range of virus strains, is proceeding as planned and is expected to continue through 2018.

**Anti-Tumor Antibody 12D7G**

XBiotech’s manufacturing development group has progressed with advancing the 12-D7G antibody cell line production system. During the quarter, the gene for 12D7G was synthesized and inserted into a cell line, which was used to produce the first set of stable clones for potential manufacturing. The candidate production cells are undergoing further selection and a high-producing cell line suitable for clinical or commercial production is expected by year end. The True Human™ antibody 12D7G binds to a tumor-related protein, NYESO-1, for which it has the potential to stimulate the body to produce a highly specific immune response against tumors. 12D7G is a candidate immunotherapy that could be used to enhance the specificity and potential efficacy of checkpoint inhibitor therapies.

***Manufacturing***

**Highlights**

XBiotech continues to optimize its upstream and downstream manufacturing processes. Process development work is ongoing to increase bioreactor volume and running time for its cell culture systems, to enhance yields and reduce costs. Ongoing optimization of our manufacturing technology reflects our continued effort to establish the lowest possible cost of goods. We believe that lowering the cost of goods for monoclonal antibodies opens up new and larger potential areas of unmet medical need. We believe that considerable opportunities exist for safe and effective medicines derived from human antibody immunity; and that some of these opportunities will require competitive pricing that will be enabled by reduced cost of goods.

This year, the Company invested in plant and equipment infrastructure and product formulation development to enable the launch of syringes that are pre-filled with bermekimab for use in subcutaneous injection. A new filling machine capable of loading syringes with bermekimab was installed at the Winnebago manufacturing center. The filling line operation was also transferred from the East Riverside Drive facility to the new filling suite at XBiotech's Winnebago campus. The first release of bermekimab-filled syringes (pre-filled and ready for use in the clinic) occurred during Q3. These syringes are already being used successfully in two ongoing clinical trials. The Company is increasing the output capacity for the syringes with a target capability to fill 1,200 syringes per day, with an annual production capacity of about 300,000 units by 2019. We believe this will be adequate output to support a market launch should an approval be granted.

During the third quarter, XBiotech began to reestablish and optimize manufacturing production of its monoclonal antibody, 514G3, for the treatment or prevention of *Staphylococcus aureus (S. aureus)* infections including MRSA. The Company expects to improve yields and processing efficiencies, and to reduce overall cost of production for 514G3 to support its initiatives to potentially use 514G3 as a prophylaxis.

***Strategic Direction***

**Highlights**

XBiotech is in clinical development with bermekimab for therapeutic indications including oncology, cardiovascular medicine, and dermatology. The Company's anti-infective antibody, 514G3, is in clinical development to treat *S. aureus* infections. Other anti-infectious disease antibodies are in pre-clinical development and are not expected to enter clinical studies before 2020.

The use of monoclonal antibodies as prophylaxis (i.e. to prevent disease) has not generally been considered a large or highly profitable business. The cost to produce antibodies is generally too large for them to be ideal for use in disease

prevention, especially when the incidence of most diseases is not frequent enough among the general population to justify relatively high unit costs. To date, therefore, most marketed monoclonal antibodies have been for therapeutic use only (to treat patients already afflicted by disease). We believe there are two crucial components for the ideal medical and commercial success of monoclonal antibodies for use in prophylaxis: a high incidence of the target disease in the population; and strong evidence of significant clinical benefit as a result of therapy. We believe that the aforementioned situation potentially exists for XBiotech's product candidates being administered prophylactically to patients with end-stage renal disease (ESRD) who are undergoing maintenance hemodialysis. In patients undergoing hemodialysis, there is a high relative incidence of cardiovascular and infectious disease-related morbidity and mortality compared to the general population. With bermekimab and 514G3, the Company has product candidates that could potentially reduce the incidence of cardiovascular and infectious disease mortality and morbidity, respectively, in this population.

**Cardiovascular Risk in ESRD**

Major adverse cardiovascular events (MACE) account for a 20% annual mortality rate in ESRD patients undergoing hemodialysis; only 35% of patients on maintenance hemodialysis will survive five years[1]. MACE is by far the leading cause of death and morbidity in this population. Clinical data, a body of scientific research, and recent discoveries (from Dr. Peter Libby's group: Folco et al. Arterioscler Thromb Vasc Biol. 2018;38:1901-1912) suggest a potential role for bermekimab in reducing MACE in ESRD patients. More than 500,000 patients are currently undergoing maintenance hemodialysis in the United States for the treatment of ESRD. Reducing cardiovascular risk in patients with ESRD is thus a major unmet medical need—for which there are no approved therapies. The successful application of bermekimab as a prophylaxis in patients receiving maintenance hemodialysis would thus represent a very important breakthrough for management of this disease.

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[1] USRDS 2013 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2014.

Beyond the importance of possibly reducing cardiovascular risk in patients suffering with ESRD, bermekimab represents a potentially unequalled opportunity for profit growth in a hemodialysis industry where there is little opportunity for growth beyond the core hemodialysis service provided. The success of bermekimab in the hemodialysis unit would also mean significant recovery of lost revenues that result from patient attrition due to cardiovascular events. Since 2011, Medicare reimbursement for new drugs in the hemodialysis business has been constrained by the implementation of the bundled payment system. Medicare's bundled payment system has created major difficulties in establishing new profit centers around drugs needed by hemodialysis patients—and it has stymied the development of new and necessary treatments for patients with ESRD. However, we believe new reimbursement strategies are possible. Medicare currently considers payment for qualifying drugs exclusively within the context of the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). In this system, only nominal additional revenue can be generated with supporting medications or agents during maintenance hemodialysis. These funding constraints are driven by the fact that drugs/substances currently reimbursed under the ESRD-PPS scheme largely provide only a *supportive* role to hemodialysis treatments. That is, there is little or no evidence that any currently approved treatments available under the ESRD-PPS system can reduce mortality events and/or reduce morbidity of patients with ESRD.

We believe that bermekimab used as a prophylaxis has the potential to reduce major cardiovascular events in ESRD patients undergoing hemodialysis. Clinical development around this "hard" clinical endpoint will largely distinguish bermekimab prophylaxis from treatments currently approved under the ESRD-PPS system and will justify consideration for substantial reimbursement. We plan to pursue discussion with important industry players regarding this opportunity.

***S. aureus* infections in ESRD**

The incidence of *S. aureus* infection in patients undergoing hemodialysis is about one hundred times that of the general population, and the bacteria accounts for about 10% of all-cause mortality in the hemodialysis population. Each year an estimated 37,000 hemodialysis patients will develop *S. aureus* infections. Of the 500,000 patients currently receiving hemodialysis in the United States, it is expected that about 40,000 will die from *S. aureus* infections over their hemodialysis careers[2].

Based on an annual prophylaxis cost of $18k per patient, there is an estimated $9 billion market potential for 514G3 in the U.S. alone for preventing *S. aureus* in patients with ESRD[3]. We believe that with potential 514G3 clinical findings for reduced mortality and morbidity due to *S. aureus*, reimbursement outside of the bundled payment system could be achieved (Please see discussion above regarding bundled reimbursement). We plan to pursue discussion with important industry players regarding this opportunity.

**Dermatology**

XBiotech has two ongoing clinical studies in dermatology, to assess bermekimab therapy in patients with Atopic dermatitis (AD) and hidradenitis suppurativa (HS). The Company believes that there continues to be considerable unmet medical need for effective treatment of both AD and HS. Moreover, recent FDA approvals of other biological

agents to treat AD and HS have provided clinical study endpoints that we believe reduce uncertainty for our clinical study designs; therefore, these endpoints are included in XBiotech's current studies. Based on outcomes of the ongoing studies, XBiotech expects to initially focus on only one indication (AD or HS) to conduct pivotal registration stud(ies). The market for dupilumab (the recently approved AD biological drug) has been estimated to be as much as $5 billion[4], and Humira (the recently approved biological drug for HS) is expected to generate $21 billion in sales by 2020[5]. Marketing approvals in either AD or HS indications for bermekimab would represent a very significant entry into the market.

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[2] Vandecasteele et al. *Staphylococcus aureus* Infections in Hemodialysis: What a Nephrologist Should Know. Clin. J. Am. Soc. Nephrology. August 2009, 4 (8) 1388-1400

[3] Based on the estimated 500,000 hemodialysis patients in the United States receiving treatment.

[4] https://www.mdmag.com/medical-news/promising-atopic-dermatitis-and-asthma-drug-fast-tracked-by-fda

[5] https://www.reuters.com/article/us-abbvie-results/abbvie-says-humira-sales-will-balloon-to-21-billion-in-2020-shares-rise-idU

**Oncology**

XBiotech continues to analyze data generated from its Phase III studies in oncology, particularly with respect to stratifying the groups to better understand which patients are likely to benefit most from bermekimab therapy. In Q3, these analyses have provided important information suggesting that patient selection based on biomarkers could significantly enhance response rates (response as defined in Hickish et al., Lancet Oncology 2017) to bermekimab therapy by nearly 50%. Analysis and manuscript preparation of these findings is being performed by our scientific board members, including leading oncologist Dr. Razelle Kurzrock, and others. The findings will be submitted for peer review and described in their entirety upon successful publication. The Company believes that these findings may provide a rationale for seeking registration or conducting further clinical work based on a biomarker-defined subgroup. The Company plans to seek FDA guidance based on these findings.

***Other Developments***

**Scientific Board**

During the quarter, XBiotech announced the addition of two leading physicians and researchers to its Scientific Advisory Board (SAB): Dr. Alice Gottlieb and Dr. Peter Libby. Both of these extraordinary scientists are world-recognized leaders in their fields.

Dr. Alice Gottlieb, M.D., Ph.D. is internationally recognized for her expertise and trail-blazing work in the development of biological therapies to treat skin diseases. She has played leading roles in the clinical development of therapies including etanercept, infliximab, ustekinumab and secukinumab. Dr. Gottlieb is working to help guide development of bermekimab for the treatment of skin diseases. She currently serves as Study Chair for XBiotech’s ongoing Phase 2 study in hidradenitis suppurativa.

Dr. Peter Libby, M.D. is the Mallinckrodt Professor of Medicine at Harvard Medical School and clinical cardiologist at Brigham and Women’s Hospital. Dr. Libby is collaborating with XBiotech on basic research into the mechanism of inflammation and the use of bermekimab to treat cardiovascular disease. Pioneering research by Dr. Libby and his team was recently published in the journal of the American Heart Association, *Arteriosclerosis, Thrombosis, and Vascular Biology*. The breakthrough findings of this research showed that bermekimab could potentially be used to prevent heart attacks and strokes.

**Intellectual Property**

XBiotech continues to aggressively expand its already extensive patent portfolio. During the quarter the Company was awarded 4 new patents and 7 patent allowances. A Canadian patent and Russian patent both cover bermekimab. Two European patents were awarded, one covering the use of IL-1 -specific antibodies for the treatment of dermatological pathologies and the other the use of IL-1 -specific antibodies for the treatment of cancer-associated cachexia. Patent applications allowed in Q3 include one each in Australia, Canada, Israel, Mexico, the Philippines, Russia, and South Korea. The allowed Australian application relates to using IL-1 -specific antibodies to treat arthritis. The allowed Canadian application relates to using IL-1 -specific antibodies to reduce a subset of blood cells that contribute to inflammatory diseases. The allowed Israeli and Mexican applications each cover key aspects of the Company's innovative True Human™ antibody discovery platform. The allowed Russian application relates to using IL-1 -specific antibodies to treat vascular diseases and complications thereof, and the allowed Philippines application relates to the Company's antibody for treating *S.aureus* infections, 514G3.

***Risks***

The Company continues to be subject to a number of risks common to companies in similar stages of development. Principal among these risks are the uncertainties of technological innovations, dependence on key individuals, development of the same or similar technological innovations by the Company's competitors and protection of proprietary technology. The Company's ability to fund its planned clinical operations, including completion of its planned clinical trials, is expected to depend on the amount and timing of cash receipts from future collaboration or product sales and/or financing transactions. The Company believes that its cash and cash equivalents of $20.8 million at September 30, 2018 will enable the Company to achieve some key inflection points, including advanced clinical studies in certain indication(s), as well as on-going R&D efforts for the Company's pre-clinical pipeline. Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our cash and cash equivalents as of September 30, 2018 will enable us to fund our operating expenses and capital expenditure requirements through 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

**Revenues**

To date, we have not generated any revenue. Our ability to generate revenue and become profitable depends on our ability to successfully commercialize our lead product candidate, bermekimab, or any other product candidate we may advance in the future.

**Research and Development Expenses**

Research and development expense consists of expenses incurred in connection with identifying and developing our drug candidates. These expenses consist primarily of salaries and related expenses, stock-based compensation, the purchase of equipment, laboratory and manufacturing supplies, facility costs, costs for preclinical and clinical research, development of quality control systems, quality assurance programs and manufacturing processes. We charge all research and development expenses to operations as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates. From inception through September 30, 2018, we have recorded total research and development expenses, including share-based compensation, of $180.8 million. Our total research and development expenses for the three months and nine months ended September 30, 2018 were $3.9 million and $10.9 million, respectively, compared to $4.9 million and $20.5 million for the three months and nine months ended September 30, 2017, respectively. Share-based compensation accounted for $0.2 million and $0.5 million for the three months and nine months ended September 30, 2018, respectively, compared to $0.2 million and $0.2 million for the three months and nine months ended September 30, 2017, respectively.

Research and development expenses, as a percentage of total operating expenses for the three months and nine months ended September 30, 2018 were 77% and 73%, respectively, compared to 75% and 77% for the three months and nine months ended September 30, 2017, respectively. The percentages, *excluding* stock-based compensation, for the three months and nine months ended September 30, 2018 were 79% and 76%, respectively, compared to 77% and 83% for the three months and nine months ended September 30, 2017, respectively.

There was a slight increase in our clinical development costs this quarter as the Company continues to progress with its two on-going phase 2 dermatology studies.

The clinical development costs may further increase going forward with potentially more advanced studies in the future as we evaluate our clinical data and pipeline.

Based on the results of our preclinical studies, we anticipate that we will select drug candidates and research projects for further development on an ongoing basis in response to their preclinical and clinical success and commercial potential. For research and development candidates in early stages of development, it is premature to estimate when material net cash inflows from these projects might occur.

**General and Administrative Expenses**

General and administrative expense consists primarily of salaries and related expenses for personnel in administrative, finance, business development and human resource functions, as well as the legal costs of pursuing patent protection of our intellectual property and patent filing and maintenance expenses, stock–based compensation, and professional fees for legal services. Our total general and administration expenses for the three months and nine months ended September 30, 2018 were $1.2 million and $4.0 million, respectively, compared to $1.7 million and $6.0 million for the three months and nine months ended September 30, 2017, respectively. Share-based compensation accounted for $0.2 million and $0.7 million for the three months and nine months ended September 30, 2018, respectively, compared to $0.2 million and $1.8 million for the three months and nine months ended September 30, 2017, respectively.

General and administrative expenses, as a percentage of total operating expenses for the three months and nine months ended September 30, 2018 were 23% and 27%, respectively, compared to 25% and 23% for the three months and nine months ended September 30, 2017, respectively. The percentages, *excluding* stock-based compensation, for the three months and nine months ended September 30, 2018 were 21% and 24%, respectively, compared to 23% and 17% for the three months and nine months ended September 30, 2017, respectively.

**Critical Accounting Policies**

The preparation of financial statements in conformity with generally accepted accounting principles requires us to make judgments, estimates and assumptions in the preparation of our consolidated financial statements and accompanying notes. Actual results could differ from those estimates. We believe there have been no significant changes in our critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2017.

**Results of Operations**

***Revenue***

We did not record any revenue during the three months or nine months ended September 30, 2018 and 2017.

***Expenses***

*Research and Development*

Research and Development costs are summarized as follows (in thousands):

| | Three Months Ended September 30, | Increase | % Increase |
|---|---|---|---|

| | 2018 | 2017 | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| Salaries and related expenses | $1,017 | $1,267 | $ (250) | -20 % |
| Laboratory and manufacturing supplies | 528 | 301 | 227 | 75 % |
| Clinical trials and sponsored research | 447 | 1,772 | (1,325) | -75 % |
| Stock-based compensation | 224 | 217 | 7 | 3 % |
| Other | 1,724 | 1,373 | 351 | 26 % |
| Total | $3,940 | $4,930 | $ (990) | -20 % |

| | Nine Months Ended September 30, | | Increase | % Increase |
|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) |
| Salaries and related expenses | $3,088 | $5,250 | $ (2,162) | -41 % |
| Laboratory and manufacturing supplies | 1,165 | 2,313 | (1,148) | -50 % |
| Clinical trials and sponsored research | 1,041 | 8,713 | (7,672) | -88 % |
| Stock-based compensation | 474 | 237 | 237 | 100 % |
| Other | 5,114 | 4,005 | 1,109 | 28 % |
| Total | $10,882 | $20,518 | $ (9,636) | -47 % |

We do not currently track our internal research and development costs or our personnel and related costs on an individual drug candidate basis. We use our research and development resources, including employees and our drug discovery technology, across multiple drug development programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs or our clinical and preclinical drug candidates.

Research and development expenses decreased by 20% to $3.9 million for the three months ended September 30, 2018 compared to $4.9 million for the three months ended September 30, 2017. Research and development expenses decreased by 47% to $10.9 million for the nine months ended September 30, 2018 compared to $20.5 million for the nine months ended September 30, 2017.

The three month decrease in research and development expenses was mainly due to a $1.3 million decrease in clinical trials and sponsored research expenses, due to the completion of a global trial in 2017 and a new study being initiated in 2018 Q2. In addition, there was a decrease in salary and related expenses due to the reduction of our research and development workforce from 49 to 44. The increase in other research and development expenses was mainly caused by the amortization of the new manufacturing equipment.

Compared to the nine months ended September 30, 2017, the research and development expense decrease in the nine months ended September 30, 2018 was primarily caused by the decrease in clinical trials and sponsored research expense, due to the completion of a global trial in 2017 and a new study being initiated in 2018. Labor costs also decreased due to the reduced size of the research and development workforce. In addition, the decrease in laboratory and manufacturing supplies expense occurred due to a reduction in clinical trial drug manufacturing. Other research and development expenses increased, due to the amortization of the new manufacturing equipment.

*General and Administrative*

General and administrative costs are summarized as follows (in thousands):

| | Three Months Ended September 30, | | Increase (Decrease) | % Increase (Decrease) |
|---|---|---|---|---|
| | 2018 | 2017 | | |
| Salaries and related expenses | $191 | $407 | $ (216) | -53% |
| Patent filing expense | 208 | 160 | 48 | 30% |
| Stock-based compensation | 215 | 228 | (13) | -6% |
| Professional fees | 210 | 440 | (230) | -52% |
| Other | 351 | 428 | (77) | -18% |
| Total | $1,175 | $1,663 | $ (488) | -29% |

| | Increase | % Increase |
|---|---|---|

| | Nine Months Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 2018 | 2017 | (Decrease) | (Decrease) | |
| Salaries and related expenses | $899 | $1,172 | $ (273) | -23 | % |
| Patent filing expense | 609 | 517 | 92 | 18 | % |
| Stock-based compensation | 712 | 1,828 | (1,116) | -61 | % |
| Professional fees | 553 | 1,168 | | | |