

XBiotech Inc.
Form 10-K/A
March 15, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

Amendment No. 1 to Form 10-K

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

For the fiscal year ended December 31, 2018

Commission file number 001-37437

XBIOTECH INC.

(Exact name of Registrant as specified in its charter)

British Columbia, Canada
(State or other jurisdiction of incorporation or organization)

N/A
(IRS Employer Identification No.)

5217 Winnebago Ln, Austin, TX 78744

(Address of principal executive offices, including zip code)

Telephone Number (512) 386-2900

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	NASDAQ Global Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of December 31, 2018, was approximately \$130,631,560, based upon the closing sales price for the registrant's common stock, as reported on the NASDAQ Global Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 10,184,898 shares of common stock the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 13, 2019, 36,047,606 shares of the registrant's Common Stock were outstanding.

EXPLANATORY NOTE

This Amendment No. 1 on Form 10-K/A is an amendment to the Annual Report on Form 10-K for the year ended December 31, 2018 (the "Report") filed with the Securities and Exchange Commission on March 14, 2019.

This Form 10-K/A is being filed for the purpose of correcting the errors regarding ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA and correcting the previously filed Certifications (filed as Exhibits 31.1 and 31.2), which inadvertently stated they were for Form 10-Q instead of Form 10-K.

Except as expressly noted herein, this Form 10-K/A does not alter any other part of the content of the Report and does not affect the information originally set forth in the Report, the remaining portions of which have not been amended.

PART II

ITEM 8. FINANCIAL STATEMENTS AND
SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of XBiotech Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of XBiotech Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2005.

Austin, Texas

March 13, 2019

XBiotech Inc.

Consolidated Balance Sheets

(in thousands, except share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$15,823	\$31,768
Prepaid expenses and other current assets	1,193	1,564
Total current assets	17,016	33,332
Property and equipment, net	27,329	29,640
Total assets	\$44,345	\$62,972
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$1,653	\$1,730
Accrued expenses	1,291	1,062
Total current liabilities	2,944	2,792
Long-term liabilities:		
Deferred rent	3	18
Total liabilities	2,947	2,810
Shareholders' equity:		
Preferred Stock, no par value, unlimited shares authorized, no shares outstanding	-	-
Common stock, no par value, unlimited shares authorized, 35,899,772 and 35,439,272 shares outstanding at December 31, 2018 and December 31, 2017, respectively	279,353	277,492
Accumulated other comprehensive loss	(255)	(768)
Accumulated deficit	(237,700)	(216,562)
Total shareholders' equity	41,398	60,162
Total liabilities and shareholders' equity	\$44,345	\$62,972

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		
	2018	2017	2016
Operating expenses:			
Research and development	\$15,725	\$26,424	\$42,486
General and administrative	5,269	7,635	10,277
Total operating expenses	20,994	34,059	52,763
Loss from operations	(20,994)	(34,059)	(52,763)
Other income (loss):			
Interest income	400	354	49
Other income	4	-	-
Foreign exchange gain (loss)	(548)	555	(47)
Total other income (loss)	(144)	909	2
Net loss	\$(21,138)	\$(33,150)	\$(52,761)
Net loss per share—basic and diluted	\$(0.59)	\$(0.95)	\$(1.63)
Shares used to compute basic and diluted net loss per share	35,804,304	34,875,814	32,403,391

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$(21,138)	\$(33,150)	\$(52,761)
Foreign currency translation adjustment	513	(825)	258
Comprehensive loss	\$(20,625)	\$(33,975)	\$(52,503)

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Shareholders' Equity

(in thousands)

	Number of Shares	Common Stock Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2015	32,279	233,902	(201)	(130,651)	103,050
Net loss	-	-	-	(52,761)	(52,761)
Foreign currency translation adjustment	-	-	258	-	258
Issuance of common stock, net of issuance cost	145	1,808	-	-	1,808
Issuance of common stock under stock option plan	204	1,136	-	-	1,136
Share-based compensation expense	-	5,573	-	-	5,573
Balance at December 31, 2016	32,628	\$242,419	\$ 57	\$(183,412)	\$59,064
Net loss	-	-	-	(33,150)	(33,150)
Foreign currency translation adjustment	-	-	(825)	-	(825)
Issuance of common stock, net of issuance cost	2,521	32,620	-	-	32,620
Issuance of common stock under stock option plan	290	818	-	-	818
Share-based compensation expense	-	1,635	-	-	1,635
Balance at December 31, 2017	35,439	\$277,492	\$ (768)	\$(216,562)	\$60,162
Net loss	-	-	-	(21,138)	(21,138)
Foreign currency translation adjustment	-	-	513	-	513
Issuance of common stock, net of issuance cost	300	-	-	-	-
Issuance of common stock under stock option plan	161	401	-	-	401
Subscription receivable	-	(200)	-	-	(200)
Share-based compensation expense	-	1,660	-	-	1,660
Balance at December 31, 2018	35,900	\$279,353	\$ (255)	\$(237,700)	\$41,398

See accompanying notes.

XBiotech Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	\$(21,138)	\$(33,150)	\$(52,761)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,433	1,484	698
Share-based compensation expense	1,660	1,750	5,573
Gain on disposal of property and equipment		-	-
Other non-cash adjustments		401	-
Changes in operating assets and liabilities:			
Prepaid expenses and other current	372	1,041	(617)
Accounts payable	(78)	(2,700)	(981)
Accrued expenses	229	(2,470)	2,066
Deferred rent	(15)	(5)	7
Net cash used in operating activities	(16,537)	(33,649)	(46,015)
Investing activities			
Purchase of property and equipment	(122)	(1,405)	(4,746)
Expenditures on building construction	-	-	(9,168)
Net cash used in investing activities	(122)	(1,405)	(13,914)
Financing activities			
Issuance of common stock and warrants, net	-	32,620	1,808
Issuance of common stock under stock option plan	201	703	1,136
Net cash provided by financing activities	201	33,323	2,944
Effect of foreign exchange rate on cash and cash equivalents	513	(825)	258
Net change in cash and cash equivalents	(15,945)	(2,556)	(56,727)
Cash and cash equivalents, beginning of period	31,768	34,324	91,051
Cash and cash equivalents, end of period	\$15,823	\$31,768	\$34,324
Supplemental Information:			
Accrued purchases of property and equipment	\$-	\$-	\$148
Accrued expenditures on building construction	-	-	439
Subscription receivable	200	-	-

See accompanying notes.

XBiotech Inc.

Notes to Consolidated Financial Statements

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 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.

Since its inception, XBiotech has focused on advancing technology to rapidly identify and clone antibodies from individuals that have resistance to disease. At the heart of the Company is a proprietary technical knowhow to translate natural human immunity into therapeutic product candidates.

In 2005, the Company began to develop a new framework for commercial manufacturing, using technology that required less capital, fewer operators and provided greater flexibility than standard industry practices.

With the manufacturing capability to produce its True Human™ antibody therapy, in 2010, the Company began a clinical trial program. The first clinical trial program at MD Anderson Cancer Center began treating the sickest cancer patients irrespective of tumor type. Soon thereafter, the Company used the same antibody therapy in various clinical studies at treatment centers around the United States (U.S.) and abroad to investigate the antibody effect in patients that had vascular disease, leukemia, type 2 diabetes, psoriasis or acne.

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 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 \$15.8 million at December 31, 2018, will enable the Company to achieve several major inflection points, including potential new clinical studies with our lead product candidate. We expect to have sufficient cash through one year from the report issuance date.

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).

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.

Prior to its initial public offering on April 15, 2015, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The board of directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including the prices at which the Company sold shares of its common stock to third parties and external market conditions affecting the biotechnology industry sector. After the initial public offering, the fair market value is calculated by using the closing price of the Company's common stock as reported by NASDAQ.

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.

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 statement 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.

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, which 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. 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 years ended December 31, 2018, 2017 and 2016 was included in the following line items on the Consolidated Statements of Operations (in thousands).

	Year Ended		
	December 31,		
	2018	2017	2016
Research and development	\$696	\$413	\$2,095
General and administrative	964	2,063	3,478
Total share-based compensation expense	\$1,660	\$2,476	\$5,573

No related tax benefits were recognized for the years ended December 31, 2018, 2017 and 2016.

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

	Year Ended		
	December 31,		
	2018	2017	2016
Weighted-average grant date fair value per share	\$4.32	\$4.85	\$7.29
Expected volatility	67% - 80%	65% - 67%	65% - 70%
Risk-free interest rate	2.38% - 3.12%	1.83% - 2.41%	1.09% - 2.44%
Expected life (in years)	1 - 10	5.38 - 10	5 - 10
Dividend yield	-	-	-

Due to the adoption of ASU No. 2016-09, "Stock Compensation" on January 1, 2017, the Company accounts for forfeitures as they occur rather than on an estimated basis.

Cash and Cash Equivalents

The Company considers highly liquid investments with a maturity of 90 days or less when purchased to be cash equivalents. Cash and cash equivalents consisted primarily of cash on deposit in U.S., German, Swiss 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 data (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 December 31, 2018 and 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 December 31, 2018 and 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 December 31, 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. We have evaluated subsequent events through the date of filing this Form 10-K.

Recent Accounting Pronouncements

In February 2016, the FASB established Topic 842, Leases, by issuing Accounting Standards Update (ASU) No. 2016-02, which supersedes ASC 840, Leases, and requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. Topic 842, as amended, (the "new lease standard") establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The effective date of the new guidance is for the Company’s first quarter of fiscal year 2019; however, early adoption is permitted. The FASB has approved an optional, alternative method to adopt the lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted the new standard effective January 1, 2019, using the alternative method. The Company will not have a cumulative adjustment impacting retained earnings. Adoption of the lease standard will not have a material impact on the Company’s consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, “Stock Compensation,” which is intended to simplify several aspects of the accounting for share-based payment award transactions. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The Company adopted this pronouncement effective January 1, 2017. Upon adoption, the Company recognized approximately \$491 thousand of accumulated excess tax benefits as deferred tax assets that under the previous guidance could not be recognized until the benefits were realized through a reduction in cash taxes paid. This part of the guidance is applied using a modified retrospective method with a cumulative-effect adjustment

to the accumulated deficit for the excess tax benefits not previously recognized. However, given the full valuation allowance placed on the additional \$491 thousand of deferred tax assets, the recognition of this provision of ASU 2016-09 had no impact to the Company's accumulated deficit as of January 1, 2017. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The Company elected to account for forfeitures as they occur using a modified retrospective transition method. The adoption of this one-time accounting policy election did not have a material impact on the Company's financial statements.

3. Property and Equipment and Building Construction in Progress

Property and equipment consisted of the following as of December 31, 2018 and 2017 (in thousands):

	2018	2017
Computer and office equipment	\$476	\$461
Furniture and fixtures	183	183
Land	1,418	1,418
Leasehold improvements	802	802
Scientific equipment	12,572	12,194
Vehicle	30	30
Building	21,013	21,013
Construction in process	201	472
Accumulated depreciation	(9,366)	(6,933)
	\$27,329	\$29,640

Depreciation expenses related to property and equipment amounted to approximately \$2.4 million, \$1.5 million, and \$0.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. Construction in process is related to research and development and manufactory equipment.

4. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2018, and 2017 (in thousands):

	2018	2017
Accrued compensation and related expenses	\$258	\$234
Accrued professional fees	92	32
Accrued clinical trial expenses	905	766
Other	36	30
	\$1,291	\$1,062

5. Common Stock

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

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 December 2018, 161 thousand shares of common stock were issued upon the exercise of stock options at a price of \$2.50 per share for a total of \$401 thousand, of which \$200 thousand is subscription receivable.

6. Common Stock Options

On November 11, 2005, the board of directors of the Company adopted a stock option plan (“the Plan”) pursuant to which the Company may grant incentive stock and non-qualified 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 this Plan 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 Plan is as follows:

	Options	Exercise Price		Weighted-Average Exercise Price
Options outstanding at December 31, 2015	4,786,577	\$0.53-	\$21.99	\$ 8.56
Granted	1,059,990	7.71 -	19.10	11.72
Exercised	(204,159)	0.74 -	19.09	5.56
Forfeitures	(453,750)	0.52 -	16.91	12.79
Options outstanding at December 31, 2016	5,188,658	\$0.52-	\$21.99	\$ 8.49
Granted	1,251,000	4.15 -	12.62	4.85
Exercised	(406,667)	0.93 -	14.71	2.28
Forfeitures	(729,367)	0.94 -	21.99	11.90
Options outstanding at December 31, 2017	5,303,624	\$2.50-	\$21.99	\$ 7.69
Granted	1,153,500	2.50 -	5.93	4.32
Exercised	(160,500)	2.50		2.50
Forfeitures	(761,185)	2.50 -	19.09	6.12
Options outstanding at December 31, 2018	5,535,439	\$2.50-	\$21.99	\$ 7.30

The weighted average fair value of the options issued to directors, employees and consultants during the fiscal years ended December 31, 2018, 2017 and 2016, was \$2.97, \$2.97 and \$7.29, respectively. Options with an intrinsic value of \$(2.22), \$(3.75) and \$1.63, became vested during 2018, 2017 and 2016, respectively. The total intrinsic value of options exercisable and total options outstanding at December 31, 2018 was \$2.1 million and \$2.9 million respectively. The total fair value of options vested during the years ended December 31, 2018, 2017 and 2016 was \$1.7 million, \$1.6 million, and \$5.7 million, respectively.

As of December 31, 2018, there was approximately \$3.0 million of unrecognized compensation cost, related to stock options granted under the Plan which will be amortized to stock compensation expense over the next 2.13 years.

7. Net Loss Per Share

The following summarizes the computation of basic and diluted net loss per share for the years ended December 31, 2018, 2017 and 2016 (in thousands, except share and per share data):

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$(21,138)	\$(33,150)	\$(52,761)
Weighted-average number of common shares—basic and diluted	35,804,304	34,875,814	32,403,391
Net loss per share—basic and diluted	\$(0.59)	\$(0.95)	\$(1.63)

The following potentially dilutive securities outstanding, prior to the use of the treasury stock method or if-converted method, have been excluded from the computation of diluted weighted-average common shares outstanding, because including them would have had an anti-dilutive effect due to the losses reported.

	Year Ended December 31,		
	2018	2017	2016
Stock options	5,535,439	5,303,624	5,188,658
Warrants to purchase common stock	-	-	-
Total	5,535,439	5,303,624	5,188,658

8. Income Taxes

The Company recorded no provision for income taxes for the years ended December 31, 2018, 2017 and 2016, due to the reported net losses in each year and reported valuation allowance.

A reconciliation of the Company's Canadian federal statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2018, 2017, and 2016:

	2018	2017	2016
Income tax benefit computed at federal tax rate	26.0 %	26.0 %	26.0 %
Change in valuation allowance	(20.3 %)	(15.3 %)	(22.1 %)
Impacts of US tax reform	-	(13.4 %)	-
Prior year true-ups	(2.3 %)	-	-
Stock compensation and other	(3.4 %)	2.7 %	(3.9 %)
Total	- %	- %	- %

During the years ended December 31, 2018, 2017 and 2016, the Company had no interest and penalties related to uncertainty in income taxes.

As of December 31, 2018, and 2017, the Company had unused net operating losses of approximately \$173.2 million (approximately \$141.7 million in Canada, \$30.9 million in the U.S., and \$0.6 million in Switzerland and Japan) and \$167.6 million (approximately \$132.3 million in Canada, \$27.7 million in the U.S., \$6.7 million in Germany and \$0.9 million in Switzerland and Japan) respectively, available to reduce taxable income of future years. The tax benefit of net operating losses begin to expire in 2025 in Canada, 2028 in U.S., 2018 in Switzerland, and 2022 in Japan.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company has established a valuation allowance due to uncertainties regarding the realization of deferred tax assets based upon the Company's lack of earnings history. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2018, 2017, and 2016 as follows (in thousands):

	2018	2017	2016
Deferred tax assets:			
Noncapital losses	\$43,474	\$41,551	\$35,064
Qualifying research and development credits	3,119	2,833	2,408
Stock based compensation	1,712	1,618	2,737

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Share issue costs	128	42	27
Accrued liabilities	229	49	286
Deferred rent	1	4	8
Total deferred tax assets	48,663	46,097	40,530
Deferred tax liabilities:			
Depreciation	166	282	31
Prepaid assets	55	-	-
Share issuance costs	-	-	-