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, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission file number 033-80623

Achieve Life Sciences, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**95-4343413**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

1040 West Georgia Street, Suite 1030, Vancouver, British Columbia, Canada V6E 4H1
(Address of Principal Executive Offices)

(604) 210-2217
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common Stock, par value $0.001 per share	ACHV	The NASDAQ Capital Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

As of November 6, 2019, there were 8,352,764 shares of the registrant's Common Stock, $0.001 par value per share, outstanding.

Achieve Life Sciences, Inc.

Index to Form 10-Q

		Page Number
Part I. Financial Information		3
Item 1	Consolidated Financial Statements (unaudited)	3
	Consolidated Balance Sheets as of September 30, 2019 (unaudited) and December 31, 2018	3
	Consolidated Statements of Loss and Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2019 and September 30, 2018	4
	Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2019 and September 30, 2018	5
	Consolidated Statements of Stockholders' Equity (unaudited) for the nine months ended September 30, 2019 and September 30, 2018	6
	Notes to Consolidated Financial Statements (unaudited)	8
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 4.	Controls and Procedures	30
Part II. Other Information		31
Item 1A.	Risk Factors	31
Item 6.	Exhibits	53
Items 2, 3 and 4 are not applicable and therefore have been omitted.		
Signatures		54

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Achieve Life Sciences, Inc.

Consolidated Balance Sheets

(Unaudited)

(In thousands, except per share and share amounts)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents *[note 5]*	$ 7,375	$ 9,515
Short-term investments *[note 5]*	—	5,089
Prepaid expenses and other assets	264	933
Total current assets	**7,639**	**15,537**
Restricted cash *[note 5]*	50	50
Property and equipment, net	64	35
Right-of-use assets *[note 7]*	372	—
Other assets	190	118
License agreement *[note 3 and 4]*	2,143	2,310
Goodwill *[note 4]*	1,034	1,034
Total assets	**$ 11,492**	**$ 19,084**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 574	$ 144
Accrued liabilities other	424	748
Accrued clinical liabilities	737	1,199
Accrued compensation	1,206	1,168
Current portion of long-term obligations *[note 7]*	198	11
Total current liabilities	**3,139**	**3,270**
Long-term obligations *[note 7]*	212	12
Total liabilities	**3,351**	**3,282**
Commitments and contingencies *[note 7]*		
Stockholders' equity:		
Series A convertible preferred stock, $0.001 par value, 5,000,000 shares authorized, zero issued and outstanding at Sept 30, 2019 and 579 issued and outstanding at December 31, 2018.	—	—
Common stock, $0.001 par value, 150,000,000 shares authorized, 8,102,764 issued and outstanding at Sept 30, 2019 and 6,721,117 issued and outstanding at December 31, 2018, respectively.	19	18
Additional paid-in capital	50,628	41,161
Accumulated deficit	(42,510)	(25,381)
Accumulated other comprehensive income	4	4
Total stockholders' equity	**8,141**	**15,802**
Total liabilities and stockholders' equity	**$ 11,492**	**$ 19,084**
Going concern *[note 1]*		

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Loss and Comprehensive Loss

(Unaudited)

(In thousands, except per share and share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
EXPENSES				
Research and development	1,824	1,541	7,911	3,787
General and administrative	1,893	1,753	5,408	5,317
Total operating expenses	3,717	3,294	13,319	9,104
OTHER INCOME (EXPENSE)				
Interest income	40	61	143	88
Other expenses	4	(7)	(25)	(34)
Total other income (expense)	44	54	118	54
Net loss	(3,673)	(3,240)	(13,201)	(9,050)
OTHER COMPREHENSIVE LOSS				
Comprehensive loss	$ (3,673)	$ (3,240)	$ (13,201)	$ (9,050)
Basic and diluted net loss per common share	$ (0.45)	$ (0.71)	$ (1.80)	$ (3.70)
Weighted average shares used in computation of basic and diluted net loss per common share	8,100,249	4,533,943	7,342,087	2,448,962

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Operating Activities:		
Net loss	$ (13,201)	$ (9,050)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization *[note 3]*	192	220
Stock-based compensation *[note 6 [c] and note 6 [d]]*	917	588
Cumulative adjustment on adoption of lease standard	(3)	—
Changes in operating assets and liabilities:		
Amounts receivable	—	(16)
Prepaid expenses and other assets	597	212
Accounts payable	430	245
Accrued liabilities other	(320)	317
Accrued clinical liabilities	(462)	(210)
Accrued compensation	39	613
Other liabilities	9	(1)
Net cash used in operating activities	(11,802)	(7,082)
Financing Activities:		
Proceeds from the sale of preferred stock, common stock and warrants, net of issuance costs	—	12,193
Proceeds from exercise of warrants, net of issuance costs	4,199	1,274
Proceeds from purchase agreement with Lincoln Park Capital, net of issuance costs	423	1,280
Net cash provided by financing activities	4,622	14,747
Investing Activities:		
Purchase of property and equipment	(52)	(36)
Proceeds on disposal of assets	—	10
Purchase of investments	(25)	(1,390)
Proceeds from maturities of investments	5,114	—
Net cash provided by (used in) investing activities	5,037	(1,416)
Effect of exchange rate changes on cash	3	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(2,140)	6,249
Cash, cash equivalents and restricted cash at beginning of the period	9,565	5,556
Cash, cash equivalents and restricted cash at end of the period	$ 7,425	$ 11,805

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Stockholders' Equity

(Unaudited)

(In thousands, except share amounts)

	Common Stock		Preferred Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total, Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2018	6,721,117	$ 18	579	$ —	$ 41,161	$ 4	$ (25,381)	$ 15,802
Restricted stock unit settlements	83	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	290	—	—	290
Adjustments to final October 2018 financing costs	—	—	—	—	4	—	—	4
Cumulative adjustment on adoption of lease standard	—	—	—	—	—	—	(3)	(3)
Net loss	—	—	—	—	—	—	(5,904)	(5,904)
Balance, March 31, 2019	6,721,200	$ 18	579	$ —	$ 41,455	$ 4	$ (31,288)	$ 10,189
Stock-based compensation expense	—	—	—	—	317	—	—	317
Shares issued - from purchase agreement with Lincoln Park Capital	124,000	—	—	—	423	—	—	423
Shares issued on exercise of warrants	1,107,813	1	—	—	4,198	—	—	4,199
Issuance of inducement warrants	—	—	—	—	3,925	—	(3,925)	—
Shares issued on conversion of preferred shares	144,750	—	(579)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(3,624)	(3,624)
Balance, June 30, 2019	8,097,763	$ 19	—	$ —	$ 50,318	$ 4	$ (38,837)	$ 11,504
Stock-based compensation expense	—	—	—	—	310	—	—	310
Restricted stock unit settlements	5,001	—	—	—	—	—	—	—
Net loss		—	—	—	—	—	(3,673)	(3,673)
Balance, September 30, 2019	8,102,764	$ 19	—	$ —	$ 50,628	$ 4	$ (42,510)	$ 8,141

	Common Stock		Preferred Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total, Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance, December 31, 2017	1,194,793	$ 12	—	$ —	$ 20,556	$ 5	$ (12,694)	$ 7,879
Stock-based compensation expense	—	—	—	—	181	—	—	181
Shares issued - from purchase agreement with Lincoln Park Capital	80,000	1	—	—	1,103	—	—	1,104
Net loss	—	—	—	—	—	—	(3,022)	(3,022)
Balance, March 31, 2018	1,274,793	$ 13	—	$ —	$ 21,840	$ 5	$ (15,716)	$ 6,142
Stock-based compensation expense	—	—	—	—	197	—	—	197
Shares issued - from purchase agreement with Lincoln Park Capital	16,000	—	—	—	174	—	—	174
Shares issued on conversion of preferred shares	1,656,750	1	(6,627)	—	2	—	—	3
Shares issued - June 2018 public offering	1,160,500	1	9,158	—	12,193	—	—	12,194
Shares issued on exercise of warrants	130,500	—	—	—	520	—	—	520
Adjustment of fractional shares on reverse stock split	(17)	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(2,788)	(2,788)
Balance, June 30, 2018	4,238,526	$ 15	2,531	$ —	$ 34,926	$ 5	$ (18,504)	$ 16,442
Stock-based compensation expense	—	—	—	—	210	—	—	210
Shares issued - from purchase agreement with Lincoln Park Capital	—	—	—	—	2	—	—	2
Shares issued on conversion of preferred shares	469,750	1	(1,879)	—	(5)	—	—	(4)
Restricted stock unit settlements	5,319	—	—	—	—	—	—	—
Shares issued on exercise of warrants	187,500	—	—	—	754	—	—	754
Net loss	—	—	—	—	—	—	(3,240)	(3,240)
Balance, September 30, 2018	4,901,095	$ 16	652	$ —	$ 35,887	$ 5	$ (21,744)	$ 14,164

See accompanying notes.

1. NATURE OF BUSINESS, BASIS OF PRESENTATION AND GOING CONCERN UNCERTAINTY

Achieve Life Sciences, Inc. (referred to as "Achieve," "we," "us," or "our") is a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation. We were incorporated in the state of Delaware, and operate out of Vancouver, British Columbia and Seattle, Washington.

On May 23, 2018, we effected a one-for-ten reverse stock split on our shares of common stock. Unless otherwise noted, impacted amounts and share information included in the financial statements and notes thereto have been retroactively adjusted for the stock split as if such stock split occurred on the first day of the first period presented. Certain amounts in the notes to the financial statements may be slightly different than previously reported due to rounding of fractional shares as a result of the reverse stock split.

The unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying unaudited consolidated financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The accompanying consolidated Balance Sheet at December 31, 2018 has been derived from the audited consolidated financial statements included in our Annual Report on Form 10-K for the year then ended. The unaudited consolidated financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2018 and filed with the United States Securities and Exchange Commission, or the SEC, on March 14, 2019.

The consolidated financial statements include the accounts of Achieve and our wholly owned subsidiaries, Achieve Life Sciences Technologies Inc., Achieve Life Science, Inc., Extab Corporation, and Achieve Pharma UK Limited. All intercompany balances and transactions have been eliminated.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business.

We have historically experienced recurring losses from operations that have generated an accumulated deficit of $42.5 million through September 30, 2019. During the three and nine months ended September 30, 2019, we incurred a net loss of $3.7 million and $13.2 million, respectively. As of September 30, 2019, we had a cash and cash equivalents balance of $7.4 million and a positive working capital balance of $4.5 million. During the nine months ended September 30, 2019, net cash used in operations was $11.8 million.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. There is no assurance that we will obtain financing from other sources. We have, thus far, financed our operations through the closing of the arrangement between us and OncoGenex Pharmaceuticals, Inc. pursuant to a Merger Agreement dated January 5, 2017, or the Arrangement, and through debt and equity financings (Note 6—Common Stock). Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidate in clinical development.

The consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

2. ACCOUNTING POLICIES

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed those estimates that we believe are critical and require the use of complex judgment in their application in our audited financial statements for the year ended December 31, 2018 in our Annual Report on Form 10-K filed with the SEC, on March 14, 2019. Since December 31, 2018, there have been no material changes to our critical accounting policies or the methodologies or assumptions we apply under them.

Recently Adopted Accounting Policies

In May 2014, the Financial Accounting Standards Board, or FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606): Revenue from Contracts with Customers, which guidance in this update will supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance when it becomes effective. ASU No. 2014-09 affects any entity that enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principal of ASU No. 2014-09 is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, which will be our fiscal year 2018 (or December 31, 2018), and entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Early adoption is permitted. We have updated our policies and procedures to reflect the adoption of ASU No. 2014-09. The adoption of this standard did not have an impact on our financial position or results of operations.

In March 2016, the FASB issued ASU 2016-09,*Improvements to Employee Share-Based Payment Accounting.* ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. For public business entities, the amendments in this Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after 15 December 2018. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In February 2016, the FASB established Topic 842, Leases, by issuing Accounting Standards Update ASU No. 2016-02, which 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. The new standard establishes a right-of-use, or ROU, model 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 were classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of loss and comprehensive loss.

We elected to adopt the standard on the effective date of January 1, 2019, using the modified retrospective method. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. We also elected the available practical expedients and implemented internal controls to enable the preparation of financial information on adoption.

The standard had a material impact on our consolidated balance sheets, but did not have an impact on our consolidated statements of loss and comprehensive loss. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases, while our accounting for finance leases remained substantially unchanged.

3. INTANGIBLES

All of our intangible assets are subject to amortization and are amortized using the straight-line method over their estimated useful life.

We acquired license and supply agreements in relation to cytisinicline upon the acquisition of Extab Corporation, or Extab, on May 18, 2015. The agreements were determined to have a fair value of $3.1 million with an estimated useful life of 14 years.

The components of intangible assets were as follows:

	September 30, 2019			December 31, 2018		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (974)	$ 2,143	$ 3,117	$ (807)	$ 2,310

For the three and nine months ended September 30, 2019, we recorded license agreement amortization expense of $0.1 million and $0.2 million, respectively. For the three and nine months ended September 30, 2018, we recorded license agreement amortization expense of $0.1 million and $0.2 million, respectively. The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2019:

Year Ending December 31,	
2019	$ 56
2020	223
2021	223
2022	223
2023	223
Thereafter	1,195
Total	**$ 2,143**

We evaluate the carrying amount of intangible assets periodically by taking into account events or circumstances that may warrant revised estimates of useful life or that indicate the asset may be impaired. We conducted an analysis of potential impairment indicators for long lived assets, including the license and supply agreements for the active pharmaceutical ingredient cytisinicline, and concluded no impairment had occurred as of September 30, 2019.

4. LICENSE AGREEMENTS

Sopharma License and Supply Agreements

In 2009 and 2010, we entered into a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma, AD, or Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries including Germany, France and Italy related to new oral dosage forms of cytisinicline providing enhanced stability. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, the trademark Tabex in all territories—other than certain countries in Central and Eastern Europe, Scandinavia, North Africa, the Middle East and Central Asia, as well as Vietnam, where Sopharma or its affiliates and agents already market Tabex—in connection with the marketing, distribution and sale of products. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-teens percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. We have agreed to cooperate with Sopharma in the defense against any actual or threatened infringement claims with respect to Tabex. Sopharma has the right to terminate the Sopharma License Agreement upon the termination or expiration of the Sopharma Supply Agreement. The Sopharma License Agreement will also terminate under customary termination provisions including bankruptcy or insolvency and material breach. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

A cross-license exists between us and Sopharma whereby we grant to Sopharma rights to any patents or patent applications or other intellectual property rights filed by us in Sopharma territories.

On May 14, 2015, we and Sopharma entered into an amendment to the Sopharma License Agreement. Among other things, the amendment to the Sopharma License Agreement reduced the royalty payments payable by us to Sopharma from a percentage in the mid-teens to a percentage in the mid-single digits and extended the term of the Sopharma License Agreement until May 26, 2029.

On July 28, 2017, we and Sopharma entered into the amended and restated Sopharma Supply Agreement. Pursuant to the amended and restated Sopharma Supply Agreement, for territories as detailed in the licensing agreement, we will exclusively purchase all of our cytisinicline from Sopharma, and Sopharma agrees to exclusively supply all such cytisinicline requested by us, and we extended the

term to 2037. In addition, we will have full access to the cytisinicline supply chain and Sopharma will manufacture sufficient cytisinicline to meet a forecast for a specified demand of cytisinicline for the five years commencing shortly after the commencement of the agreement, with the forecast to be updated regularly thereafter. Each of us and Sopharma may terminate the Sopharma Supply Agreement in the event of the other party's material breach or bankruptcy or insolvency.

University of Bristol License Agreement

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives for use in smoking cessation, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level. Any patents issued in connection with these applications would be scheduled to expire on February 5, 2036 at the earliest.

In consideration of rights granted by the University of Bristol, we agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize product candidates subject to the University of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement, we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we agreed to pay an initial amount of $37,500 upon the execution of the amended University of Bristol License Agreement, and additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the amended University of Bristol License Agreement, in addition to amounts under the original University of Bristol License Agreement of up to $3.2 million in the aggregate, tied to specific financing, development and commercialization milestones. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible, as provided in the original University of Bristol License Agreement, for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Up to September 30, 2019, we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Unless otherwise terminated, the University of Bristol License Agreement will continue until the earlier of July 2036 or the expiration of the last patent claim subject to the University of Bristol License Agreement. We may terminate the University of Bristol License Agreement for convenience upon a specified number of days' prior notice to the University of Bristol. The University of Bristol License Agreement will terminate under customary termination provisions including bankruptcy or insolvency or its material breach of the agreement. Under the terms of the University of Bristol License Agreement, we provided 100 grams of cytisinicline to the University of Bristol as an initial contribution.

5. FAIR VALUE MEASUREMENTS

Assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. For certain of our financial instruments including amounts receivable and accounts payable the carrying values approximate fair value due to their short-term nature.

ASC 820 "Fair Value Measurements and Disclosures" specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. In accordance with ASC 820, these inputs are summarized in the three broad levels listed below:

- Level 1 – Quoted prices in active markets for identical securities.
- Level 2 – Other significant inputs that are observable through corroboration with market data (including quoted prices in active markets for similar securities).
- Level 3 – Significant unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability.

As quoted prices in active markets are not readily available for certain financial instruments, we obtain estimates for the fair value of financial instruments through third-party pricing service providers.

In determining the appropriate levels, we performed a detailed analysis of the assets and liabilities that are subject to ASC 820.

We invest our excess cash in accordance with investment guidelines that limit the credit exposure to any one financial institution other than securities issued by the U.S. Government. These securities are not collateralized and mature within one year.

A description of the valuation techniques applied to our financial instruments measured at fair value on a recurring basis follows.

Financial Instruments

Cash

Significant amounts of cash are held on deposit with large well-established U.S. and Canadian financial institutions.

Money Market Securities

Money market securities are classified within Level I of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities.

U.S. Government and Agency Securities

U.S. Government Securities U.S. government securities are valued using quoted market prices. Valuation adjustments are not applied. Accordingly, U.S. government securities are categorized in Level 1 of the fair value hierarchy.

U.S. Agency Securities U.S. agency securities are comprised of two main categories consisting of callable and non-callable agency issued debt securities. Non-callable agency issued debt securities are generally valued using quoted market prices. Callable agency issued debt securities are valued by benchmarking model-derived prices to quoted market prices and trade data for identical or comparable securities. Actively traded non-callable agency issued debt securities are categorized in Level 1 of the fair value hierarchy. Callable agency issued debt securities are categorized in Level 2 of the fair value hierarchy.

Corporate and Other Debt

Corporate Bonds and Commercial Paper The fair value of corporate bonds and commercial paper is estimated using recently executed transactions, market price quotations (where observable), bond spreads or credit default swap spreads adjusted for any basis difference between cash and derivative instruments. The spread data used are for the same maturity as the bond. If the spread data does not reference the issuer, then data that reference a comparable issuer are used. When observable price quotations are not available, fair value is determined based on cash flow models with yield curves, bond or single name credit default swap spreads and recovery rates based on collateral values as significant inputs. Corporate bonds and commercial paper are generally categorized in Level 2 of the fair value hierarchy; in instances where prices, spreads or any of the other aforementioned key inputs are unobservable, they are categorized in Level 3 of the hierarchy.

The following table presents information about our assets and liabilities that are measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value (in thousands):

September 30, 2019	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 1,724	$ —	$ —	$ 1,724
Money market securities (cash equivalents)	5,651	—	—	5,651
Restricted cash	50	—	—	50
Corporate bonds and commercial paper (short term investments)	—	—	—	—
Total assets	**$ 7,425**	**$ —**	**$ —**	**$ 7,425**

Cash, cash equivalents and short-term investments consist of the following (in thousands):

September 30, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 1,724	$ —	$ —	$ 1,724
Money market securities	5,651	—	—	5,651
Total cash and cash equivalents	**$ 7,375**	**$ —**	**$ —**	**$ 7,375**
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	**$ 50**	**$ —**	**$ —**	**$ 50**
Corporate bonds and commercial paper	—	—	—	—
Total short-term investments	**$ —**	**$ —**	**$ —**	**$ —**

Our gross realized gains and losses on sales of available-for-sale securities were not material for the three and nine months ended September 30, 2019 and 2018.

We only invest in A (or equivalent) rated securities. All securities included in cash and cash equivalents had maturities of 90 days or less at the time of purchase. All securities included in short-term investments have maturities of within one year of the balance sheet date. The cost of securities sold is based on the specific identification method.

6. COMMON STOCK

[a] Authorized

150,000,000 authorized common shares, par value of $0.001, and 5,000,000 preferred shares, par value of $0.001.

On May 22, 2018, we filed an amendment to our Articles of Incorporation and effected as of May 23, 2018 a one-for-ten reverse stock split of our issued and outstanding shares of common stock, $0.001 par value, and a certificate of amendment to our Second Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 75,000,000 to 150,000,000.

[b] Issued and outstanding shares

Purchase Agreement and Financing with Lincoln Park Capital

On September 14, 2017 we and Lincoln Park Capital Fund, LLC, or LPC, entered into a share and unit purchase agreement, or Purchase Agreement, pursuant to which we have the right to sell to LPC up to $11.0 million in shares of our common stock, par value $0.001 per share, subject to certain limitations and conditions set forth in the Purchase Agreement. On May 22, 2018 we obtained the requisite stockholder authorization to sell shares of our common stock to LPC in excess of 20% of our outstanding shares of common stock (as of the date we entered into the purchase agreement) in order to be able to sell to LPC the full amount remaining under the purchase agreement.

Pursuant to the Purchase Agreement, LPC initially purchased 32,895 of our units, or the Units, at a purchase price of $30.40 per unit, with each Unit consisting of (a) one share of our Common Stock and (b) one warrant to purchase one-quarter of a share of Common Stock at an exercise price of $34.96 per share, or Warrant. Each Warrant is exercisable six months following the issuance date until the date that is five years and six months after the issuance date and is subject to customary adjustments. The Warrants were issued only as part of the Units in the initial purchase of $1.0 million and no warrants shall be issued in connection with any other purchases of common stock under the Purchase Agreement.

After the initial purchase, if our stock price is above $1.00, as often as every other business day over the 30-month term of the Purchase Agreement, and up to an aggregate amount of an additional $10.0 million (subject to certain limitations) of shares of common stock, we have the right, from time to time, in our sole discretion and subject to certain conditions to direct LPC to purchase up to 8,000 shares of common stock with such amounts increasing as the closing sale price of our common stock as reported on The Nasdaq Capital Market increases. The purchase price of shares of common stock pursuant to the Purchase Agreement will be based on prevailing market prices of common stock at the time of sales without any fixed discount, and we will control the timing and amount of any sales of common stock to LPC. In addition, we may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below $20.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 12,352 shares of common stock; no cash proceeds were received from the issuance of

these shares. The consideration of 12,352 shares of our common stock were fair valued based on the closing price of our common stock as at the transaction date and recognized as part of offering expenses.

During the three and nine months ended September 30, 2019, we offered and sold zero and 124,000, respectively, shares of our common stock pursuant to the Purchase Agreement with LPC for gross proceeds of approximately $0.4 million. Since entry into the Purchase Agreement, from September 14, 2017 through September 30, 2019, we offered and sold an aggregate of 307,378 shares of our common stock, including the 32,895 shares that were part of the initial purchase of Units. These aggregate sales resulted in gross proceeds to us of approximately $4.1 million and offering expenses of $0.5 million. As of September 30, 2019, shares of our common stock having an aggregate value of approximately $6.9 million remained available for sale under this offering program.

From October 1, 2019 through November 6, 2019, we offered and sold 250,000 shares of our common stock pursuant to our Purchase Agreement with LPC. These sales resulted in gross proceeds to us of approximately $0.4 million. As of November 6, 2019 shares of our common stock having an aggregate value of approximately $6.6 million remained available for sale under this offering program

June 2018 Public Offering

On June 19, 2018, we completed an underwritten registered public offering, pursuant to which we sold 710,500 Class A Units at a price per unit of $4.00 and 9,158 Class B Units at a price per unit of $1,000.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series A Convertible Preferred Stock par value $0.001 per share, convertible at any time at the holder's option into 250 shares of common stock and warrants to purchase 250 shares of common stock.

Each warrant was immediately exercisable, expires on the five year anniversary of the date of issuance and is exercisable at a price per share of common stock of $4.00. Additionally, subject to certain exceptions, if, after June 19, 2018, (i) the volume weighted average price of our common stock for each of any 30 consecutive trading days, or the Measurement Period, which Measurement Period commences on June 19, 2018, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then we may call for cancellation of all or any portion of the warrants then outstanding.

The Class A Units and Class B Units were not certificated and the shares of common stock, Series A Convertible Preferred Stock and warrants comprising such Units were immediately separable and were issued separately in the public offering. The Class A and B Units were offered by us pursuant to (i) the registration statement on Form S-1 (File No. 333-224840), and each amendment thereto, which was initially filed with the SEC, on May 10, 2018 and declared effective by the SEC on June 14, 2018, and the registration statement on Form S-1 (File No. 333- 225649) filed by the us with the SEC pursuant to Rule 462(b) of the Securities Act of 1933, as amended, or the Securities Act, on June 14, 2018.

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or the Underwriter, on June 15, 2018, we granted the Underwriter a 45 day option, or the Overallotment Option, to purchase up to 450,000 additional shares of common stock and/or warrants to purchase up to 450,000 shares of Common Stock solely to cover over-allotments. The Overallotment Option was exercised in full on June 18, 2018.

The public offering raised total gross proceeds of $13.8 million and after deducting $1.6 million in underwriting discounts and commissions and offering expenses, we received net proceeds of $12.2 million

The underwriting discounts and commissions and offering expenses have been charged against the gross proceeds.

As of September 30, 2019, all 9,158 shares of the Series A Convertible Preferred Stock had been converted into 2,289,500 shares of common stock, and no shares of the Series A Convertible Preferred Stock remained outstanding.

October 2018 Registered Direct Offering

On October 3, 2018 we completed a registered direct offering, pursuant to which we sold 1,789,258 shares of common stock at a price of $3.1445. We also issued to the investors in a concurrent private placement unregistered warrants to purchase up to 0.5 shares of common stock for each share purchased in the registered direct offering with an exercise price of $3.1445 per share. The warrants were exercisable immediately upon issuance and will expire five years following the date of issuance.

The registered direct offering raised total gross proceeds of $5.6 million, and after deducting approximately $0.6 million in placement agent fees and offering expenses, we received net proceeds of $5.0 million.

The placement agent fees and offering expenses have been charged against the gross proceeds.

At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On June 7, 2019, we entered into an At The Market Offering Agreement, or the Offering Agreement, with H.C. Wainwright & Co., LLC, as agent, or H.C. Wainwright, pursuant to which we may offer and sell, from time to time and at our election, through H.C. Wainwright shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $6.0 million.

Pursuant to the Offering Agreement, H.C. Wainwright may sell the shares our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers' transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares of common stock from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

We are not obligated to make any sales of the shares of common stock under the Offering Agreement. The offering of shares of common stock pursuant to the Offering Agreement will terminate upon the earliest of (a) the sale of all of the shares of common stock subject to the Offering Agreement, (b) the termination of the Offering Agreement by H.C. Wainwright or us, as permitted therein, or (c) June 7, 2022.

We will pay H.C. Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of shares of common stock and have agreed to provide H.C. Wainwright with customary indemnification and contribution rights. We will also reimburse H.C. Wainwright for certain specified expenses in connection with entering into the Offering Agreement. The Offering Agreement contains customary representations and warranties and conditions to the placements of the shares of common stock pursuant thereto.

From June 7, 2019 to September 30, 2019 we did not offer any shares of our common stock for sale pursuant to the Offering Agreement. As of September 30, 2019, shares of our common stock having an aggregate value of approximately $6.0 million remained available for sale under the Offering Agreement.

The offering expenses and fees have been deferred and will be charged against gross proceeds.

Equity Award Issuances and Settlements

During the three and nine months ended September 30, 2019, we issued no shares of common stock to satisfy stock options exercises and 5,134 shares of common stock to satisfy restricted stock unit settlements, compared with no shares of common stock issued to satisfy stock options exercises and 5,340 shares of common stock to satisfy restricted stock unit settlements, during the three and nine month periods ended September 30, 2018, respectively.

[c] Stock options

2018 Equity Incentive Plan

As of September 30, 2019, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 1,336,055 common shares for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 732,000 were reserved for options currently outstanding and 604,055 were available for future equity grants.

Under the 2018 Plan, we may grant options to purchase common shares or restricted stock units to our employees, directors, officers and consultants. The exercise price of the options is determined by our board of directors but will be at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option is set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2018 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

2017 Equity Incentive Plan

As of September 30, 2019, we had reserved, pursuant to the 2017 Equity Incentive Plan, or the 2017 Plan, 272,660 common shares for issuance upon exercise of stock options, currently outstanding, by employees, directors and officers of ours. Upon the effectiveness of our 2018 Plan, we ceased granting equity awards under our 2017 Plan.

Under the 2017 Plan, we granted options to purchase common shares or restricted stock units to our employees, directors, officers and consultants. The exercise price of the options was determined by our board of directors but was at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option was set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2017 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

2010 Performance Incentive Plan

As of September 30, 2019, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 15,931 common shares for issuance upon exercise of stock options and settlement of restricted stock units by employees, directors, officers and consultants of ours, of which 5,923 were reserved for options currently outstanding and 10,008 were reserved for restricted stock units currently outstanding.

Under the 2010 Plan we granted options to purchase common shares and restricted stock units to our employees, directors, officers and consultants. The exercise price of the options was determined by our board of directors and was at least equal to the fair value of the common shares at the grant date. The options vest in accordance with terms as determined by our board of directors, typically over three to four years for options issued to employees and consultants, and over one to three years for members of our board of directors. The expiry date for each option is set by our board of directors with a maximum expiry date of ten years from the date of grant. In addition, the 2010 Plan allows for accelerated vesting of outstanding equity awards in the event of a change in control. The terms for accelerated vesting, in the event of a change in control, is determined at our discretion and defined under the employment agreements for our officers and certain of our employees.

Stock Option Summary

We grant stock options that vest over time in accordance with terms as determined by our Board of Directors, or the Board, which terms are typically four years for employee and consultant grants and one to three years for Board option grants. We also grant stock option awards that vest in conjunction with certain performance conditions to executive officers, employees and consultants. At each reporting date, we are required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance condition. The expiry date for each option is set by the Board, which is typically seven to ten years. The exercise price of the options is determined by the Board.

Stock option transactions and the number of stock options outstanding are summarized below:

	Number of Optioned Common Shares	Weighted Average Exercise Price
Balance, December 31, 2018	**665,585**	**$ 15.65**
Granted	345,350	1.73
Balance, September 30, 2019	**1,010,935**	**$ 10.90**

The fair value of each stock award for employees and directors is estimated on the grant date and for consultants at each reporting period, using the Black-Scholes option-pricing model based on the weighted-average assumptions noted in the following table:

	Nine Months Ended September 30,	
	2019	2018
Risk-free interest rates	2.52 %	2.93 %
Expected dividend yield	0 %	0 %
Expected life	5.97	5.68
Expected volatility	94.25 %	88.23 %

The expected life was calculated based on the simplified method as permitted by the SEC's Staff Accounting Bulletin 110,*Share-Based Payment*. We consider the use of the simplified method appropriate because of the lack of sufficient historical exercise data following the Arrangement. The computation of expected volatility was based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a U.S.

Treasury instrument whose term is consistent with the expected life of the stock options. In addition to the assumptions above, as required under ASC 718, management made an estimate of expected forfeitures and is recognizing compensation costs only for those equity awards expected to vest. Forfeiture rates are estimated using historical actual forfeiture rates. These rates are adjusted on a quarterly basis and any change in compensation expense is recognized in the period of the change. We have never paid or declared cash dividends on our common stock and do not expect to pay cash dividends in the foreseeable future.

The results for the periods set forth below included share-based compensation expense for stock options and restricted stock units in the following expense categories of the consolidated statements of loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 89	$ 70	$ 275	$ 190
General and administrative	$ 221	140	642	398
Total stock-based compensation	$ 310	$ 210	$ 917	$ 588

As of September 30, 2019 and December 31, 2018, the total unrecognized compensation expense related to stock options granted was $2.1 million and $1.8 million, respectively, which is expected to be recognized as expense over a period of approximately 2.3 years from September 30, 2019.

For the three and nine months ended September 30, 2019, a total of 5,137,655 shares, consisting of 4,116,712 warrants, 1,010,935 options and 10,008 restricted stock units, have not been included in the loss per share computation, as their effect on diluted per share amounts would have been anti-dilutive. For the same periods in 2018, a total of 3,854,505 shares underlying options, restricted stock units and warrants have not been included in the loss per share computation.

[d] Restricted Stock Unit Awards

We grant restricted stock unit awards that generally vest and are expensed over a four year period. We also grant restricted stock unit awards that vest in conjunction with certain performance conditions to certain executive officers, key employees and consultants. At each reporting date, we are required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon our assessment of accomplishing each performance condition. For the three and nine months ended September 30, 2019, we recorded a compensation expense of $36,000 and $0.1 million, respectively, related to these awards, compared to $37,000 and $0.1 million for the three and nine months ended September 30, 2018, respectively.

The following table summarizes our restricted stock unit award activity during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, December 31, 2018	**15,142**	**$ 30.53**
Released	(5,134)	33.54
Balance, September 30, 2019	**10,008**	**$ 28.99**

As of September 30, 2019, we had approximately $0.3 million in total unrecognized compensation expense related to our restricted stock unit awards that is to be recognized over a weighted-average period of approximately 1.84 years.

[e] Non-employee options and restricted stock units

We recognize non-employee stock-based compensation expense over the period of expected service by the non-employee. As the service is performed, we are required to update our valuation assumptions, re-measure unvested options and restricted stock units and record the stock-based compensation using the valuation as of the vesting date. This differs from the accounting for employee awards where the fair value is determined at the grant date and is not subsequently adjusted. This re-measurement may result in higher or lower stock-based compensation expense in the Consolidated Statements of Loss and Comprehensive Loss. As such, changes in the market price of our stock could materially change the value of an option or restricted stock unit and the resulting stock-based compensation expense.

[f] Common Stock Warrants

On May 30, 2019, we entered into a Warrant Exercise Agreement, or the Exercise Agreement, with Armistice Capital Master Fund, Ltd., or Armistice. Pursuant to the Exercise Agreement, Armistice exercised (i) outstanding warrants to purchase 270,313 shares of our common stock, par value $0.001 per share, with an exercise price of $3.1445 per share issued as part of the October 2018 financing and (ii) outstanding warrants to purchase 837,500 shares of our common stock with an exercise price of $4.00 per share issued as part of the June 2018 financing, for aggregate exercise proceeds to us of approximately $4.2 million, or, collectively, the Warrant Exercise.

As an inducement for the Warrant Exercise, we agreed to issue to Armistice a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of our common stock at an exercise price of $4.50 per share. We also agreed to file a registration statement covering the resale of the New Warrant Shares. The New Warrant and New Warrant Shares were offered to Armistice in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act of 1933.

Under ASC 260, the fair value of the new warrants of $3.9 million was recognized into accumulated deficit on our consolidated balance sheet as at September 30, 2019. We determined the fair value of the new warrants using the Black-Scholes pricing model with the following assumptions: stock price of $4.23, volatility of 97.16%, risk-free interest rate of 2.06% and expected term of six years.

The following is a summary of outstanding warrants to purchase common stock atSeptember 30, 2019:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A-1 Warrants issued in April 2015 financing	2,175	264.0000	October 2020
(2) Warrants issued in September 2017 financing	8,224	34.9600	March 2023
(3) Warrants issued in June 2018 financing	2,282,000	4.0000	June 2023
(4) Warrants issued in October 2018 financing	624,313	3.1445	October 2023
(5) Warrants issued in May 2019	1,200,000	4.5000	May 2025

For the nine months ended September 30, 2019, 837,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of $3.4 million and 270,313 of the warrants issued in the October 2018 financing were exercised at a per unit price of $3.1445, for proceeds of $0.8 million. For the nine months ended September 30, 2018, 130,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of $0.5 million. The Series A-1 Warrants assumed by us as part of the Arrangement, the warrants issued in the September 2017 financing, the warrants issued in the June 2018 financing, the warrants issued in the October 2018 registered direct offering and the warrants issued as part of the Exercise Agreement in May 2019, are classified as equity.

7. COMMITMENTS AND CONTINGENCIES

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

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Vancouver office operating lease	$ 214	$ 16	$ 128	$ 70	$ —
Seattle office operating lease	$ 209	$ 36	$ 173	$ —	$ —
Total	**$ 423**	**$ 52**	**$ 301**	**$ 70**	**$ —**

Leases

We have operating leases for our corporate offices.

Operating leases with a term of 12 months or longer are included in ROU assets, other current liabilities, and operating lease liabilities on our consolidated balance sheets. Finance leases are included in property and equipment, other current liabilities, and other long-term liabilities on our consolidated balance sheets.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As most of our leases do not provide an implicit rate, we use the incremental borrowing rate of comparable companies from a representative peer group selected based on industry and market capitalization. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. Our

lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Vancouver lease arrangements

We had a lease agreement for office space in Vancouver, British Columbia, which expired in January 2019. Pursuant to the lease agreement, we had the option to terminate the lease early without penalty at any time after January 1, 2017 so long as we provide three months prior written notice to the landlord. This lease was not renewed. This lease was classified as an operating lease.

On November 19, 2018, we entered into a lease agreement, or the Vancouver Lease, for new office space in Vancouver, British Columbia, which commenced on February 1, 2019. Pursuant to the terms of the lease agreement, we leased approximately 2,367 square feet located at Suite 1030, The Grosvenor Building, 1040 West Georgia Street, Vancouver, B.C. The initial term of the Vancouver Lease will expire on January 31, 2023, with an option to extend the term for one further four-year period, at a base rent as agreed upon between the parties with a minimum value equal to the base rent payable in the last year of the initial term. The monthly base rent for the premises was approximately $5,200 commencing on February 1, 2019, and on February 1, 2021, will increase up to approximately $5,400. The landlord provided us with a construction allowance of approximately $14,200. In addition, we paid a security deposit of approximately $18,600 upon entering into the lease agreement. The security deposit was reduced by the first month's rent and operating expenses upon commencement of the Vancouver Lease. The Vancouver Lease was classified as an operating lease.

Future minimum lease payments under the Vancouver lease are as follows (in thousands):

2019	$	16
2020		63
2021		65
2022		65
2023		5
Total	**$**	**214**

Seattle lease arrangement

On December 11, 2017, we entered into a lease, or the Seattle Lease, with 520 Pike Street, Inc., or Pike, pursuant to which we leased approximately 3,187 square feet located at Suite 2250 at 520 Pike Tower, Seattle, Washington, 98101, which commenced on March 1, 2018. The initial term of the Seattle Lease will expire at the end of the month on the third anniversary of the Seattle Lease.

Our monthly base rent for the premises started at approximately $11,685 which commenced on March 1, 2018 and will increase on an annual basis up to approximately $12,397. In addition, we paid a security deposit to Pike in the amount of $37,192, subject to periodic reductions in the amount of $12,397 after each of the first and second anniversaries of the Seattle Lease, which Pike may retain for base rent or other damages, in the event of our default under the Seattle Lease.

We may not assign or sublet all or any portion of the premises without the consent of Pike, and Pike shall be entitled to 50% of any profit which we may receive above and beyond the rental price of the Seattle Lease. Upon receipt of notice of our intent to assign or sublease any portion of the leased premises, Pike may terminate that portion of the premises within 30 days, and provided, that if such portion constitutes 50% or more of the total square footage of the premises, Pike may terminate the Seattle Lease in its entirety. The Seattle Lease was classified as an operating lease.

The future minimum annual lease payments under the Seattle Lease are as follows (in thousands):

2019	$	36
2020		148
2021		25
Total	**$**	**209**

Consolidated lease and operating expense relating to the Vancouver, British Columbia, and Seattle, Washington offices for the three and nine months ended September 30, 2019 was $0.1 million and $0.2 million, respectively. Consolidated rent expense for the three and nine months ended September 30, 2018 was $0.1 million and $0.2 million, respectively.

Other information related to leases was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Supplemental Cash Flows Information				
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 42	$ —	$ 133	$ —
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	—	—	$ 455	—
Weighted Average Remaining Lease Term				
Operating leases	2.36 years	—	2.36 years	—
Weighted Average Discount Rate				
Operating leases	9.97%	—	9.97%	—

Guarantees and Indemnifications

We indemnify our officers, directors and certain consultants for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at its request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime.

The maximum amount of potential future indemnification is unlimited; however, we have obtained director and officer insurance that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations as of September 30, 2019.

We have certain agreements with certain organizations with which we do business that contain indemnification provisions pursuant to which we typically agree to indemnify the party against certain types of third-party claims. We accrue for known indemnification issues when a loss is probable and can be reasonably estimated. There were no accruals for or expenses related to indemnification issues for any period presented.

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

INFORMATION REGARDING FORWARD LOOKING STATEMENTS

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, business strategies, cost savings, objectives of management and other statements that are not historical facts. You can find many of these statements by looking for words like "believes," "expects," "anticipates," "estimates," "may," "should," "will," "could," "plan," "intend" or similar expressions in this document or in documents incorporated by reference into this document. We intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- our ability to continue as a going concern, our anticipated future capital requirements and the terms of any capital financing agreements;
- progress and preliminary and future results of any clinical trials;
- anticipated regulatory filings, requirements and future clinical trials;
- timing and amount of future contractual payments, product revenue and operating expenses; and
- market acceptance of our products and the estimated potential size of these markets.

These forward-looking statements are based on the current beliefs and expectations of our management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. Factors that might cause such a difference include those discussed in Item 1A "Risk Factors," as well as those discussed elsewhere in the Quarterly Report on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Overview

We are a clinical-stage pharmaceutical company committed to the global (excluding Central & Eastern Europe plus other territories) development and commercialization of cytisinicline for smoking cessation and nicotine addiction. The United States Adopted Names Council adopted cytisinicline as the nonproprietary, or generic, name for the substance also known as cytisine during the third quarter of 2018. Our primary focus is to address the global smoking and nicotine addiction epidemic, which is a leading cause of preventable death and is responsible for more than eight million deaths annually worldwide. We may expand our focus to include how to address other methods of nicotine addiction such as e-cigarettes/vaping.

Our management team has significant experience in growing emerging companies focused on the development of under-utilized pharmaceutical compounds to meet unmet medical needs. We intend to use this experience to develop and ultimately commercialize cytisinicline either directly or via strategic collaborations.

Cytisinicline is an established smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by Sopharma AD for over 20 years under the brand name Tabex™. It is estimated that over 20 million people have used cytisinicline to help treat nicotine addiction, including over 2,000 patients in investigator-conducted, Phase 3 clinical trials in Europe and New Zealand. Both trials were published in the New England Journal of Medicine in September 2011 and December 2014, respectively.

Cytisinicline is a naturally occurring, plant-based alkaloid from the seeds of the Laburnum anagyroides plant. Cytisinicline is structurally similar to nicotine and has a well-defined, dual-acting mechanism of action that is both agonistic and antagonistic. It is believed to aid in smoking cessation and the treatment of nicotine addiction by interacting with nicotine recep tors in the brain by reducing the severity of nicotine withdrawal symptoms through agonistic binding to nicotine receptors and by reducing the reward and satisfaction associated with nicotine through antagonistic properties.

Non-clinical toxicology studies were sponsored by the National Center for Complementary and Integrative Health, or NCCIH, a division of the National Institutes of Health, or NIH, and by the National Cancer Institute, or NCI, to assist in our Investigational New Drug Application, or IND. In June 2017, we filed our IND application for cytisinicline with the United States Food and Drug Administration, or FDA, which included the NCCIH sponsored non-clinical studies. Additional non-clinical reproductive toxicology studies are also being conducted by NCCIH and NCI, with two such studies already submitted to the IND and a third study to be submitted upon completionOther non-clinical toxicology studies that will be required for a New Drug Application, or NDA, include two longer-term chronic toxicology studies and two carcinogenicity studies, which are in distinct stages of execution as Achieve Sponsored studies. One of the chronic toxicology studies has been completed and submitted to FDA, while the second chronic toxicology study is in progress and is expected to be completed in 2020. Additionally, one of the carcinogenicity studies is currently in progress, while the second carcinogenicity study is planned for initiation during Phase 3 development.

In August 2017, we initiated the Phase 1 clinical study evaluating the effect of food on the bioavailability of cytisinicline in normal healthy volunteers. We completed the food effect study and announced the results in November of 2017 demonstrating similar bioavailability of cytisinicline in fed and fasted subjects.

In October 2017, we initiated a clinical study assessing the repeat-dose pharmacokinetics, or PK, and pharmacodynamics, or PD, effects of 1.5 mg and 3.0 mg cytisinicline in 36 healthy volunteer smokers when administered over the standard 25-day course of treatment as marketed by Sopharma in their territories. Of the 36 subjects, 24 were to be 18-65 years of age and 12 were to be greater than 65 years of age. Final results were presented at the Annual Meeting of the Society for Research on Nicotine and Tobacco, or SRNT, in February 2019. The study randomized a total of 26 subjects, which included only 2 of the intended 12 subjects of an age greater than 65, due to difficulty enrolling within this age group. All 26 subjects completed the study. Predictable increases in plasma cytisinicline concentrations were observed with increasing unit dosing from 1.5 mg to 3.0 mg. Smokers in the study were not required to have a designated or predetermined quit date. Overall, subjects had an 80% reduction in cigarettes smoked, 82% reduction in expired carbon monoxide, and 46% of the subjects achieved biochemically verified smoking abstinence by day 26. Subjects who received 3.0 mg cytisinicline over the 25 days had a trend for higher smoking abstinence compared to subjects who received 1.5 mg cytisinicline. The adverse events, or AEs, observed were mostly mild with transient headaches as the most commonly reported event. No severe or serious AEs were observed in the study.

In December 2017, we initiated a series of drug metabolism, drug-to-drug interaction, and transporter studies of cytisinicline and results from these studies were announced in June 2018. These studies demonstrated that cytisinicline has no clinically significant interaction with any of the hepatic enzymes commonly responsible for drug metabolism nor clinically significant interaction with drug transporters. This suggests that cytisinicline may be administered with other medications without the need to modify the dose of any co-administered medications. We will continue to evaluate any new FDA guidance on whether additional drug-to-drug interactions studies will be required prior to a future NDA filing.

We have met with the FDA and with other national regulatory authorities in Europe to identify the steps required for the approval of cytisinicline. We held an end of Phase 2 meeting with the FDA in May 2018 to review and receive guidance on our Phase 3 clinical program and overall development plans for cytisinicline to support an NDA. This review included submitted results from non-clinical studies, standard drug-to-drug interaction and reproductive/teratogenicity studies. Detailed plans for chronic toxicology, carcinogenicity studies, and additional clinical studies regarding renal impairment, QT interval prolongation, longer term exposure and adequate demonstration of safety and efficacy from our planned randomized, placebo-controlled, Phase 3 clinical trials were also discussed.

In 2018, Sopharma commercially launched a newly formulated cytisinicline tablet with improved shelf life in their territories. In May 2018, we initiated a study to evaluate the effect of food on the bioavailability of cytisinicline in volunteer smokers using this new formulation and data results were announced in September 2018. The study demonstrated similar bioavailability of cytisinicline in fed and fasted subjects. Cytisinicline was extensively absorbed after oral administration with maximum cytisinicline concentration levels observed in the blood within less than two hours with or without food. Total excretion levels of cytisinicline also remained equivalent in both the fed and fasted states, and the 3.0 mg dose using this new formulation of cytisinicline was well tolerated.

In December 2018, we announced that the FDA was in agreement with our Initial Pediatric Study Plan, specifically, providing a full waiver for evaluating cytisinicline in a pediatric population. The reasons for the full waiver were based on the low numbers of children smoking under the age of 12 and the logistical difficulties of recruiting treatment-seeking smokers in the adolescent age group. The agreed upon Initial Pediatric Study Plan is expected to be included as part of our future application for marketing approval of cytisinicline.

In March 2019, we initiated a clinical trial to assess the dose limiting AEs that would define the maximum tolerated dose, or MTD, for a single administered oral dose of cytisinicline. This study evaluated smokers who received one single dose of cytisinicline. The starting dosage of cytisinicline was 6.0 mg and was to be increased in separate groups of subjects for each escalated dose level until stopping criteria (based on the occurrence of dose-limiting AEs) were reached. A safety review after each dose level was performed by an independent Data Safety Monitor Committee, or DSMC, before escalation to the next dose level. Six dose levels were pre-

planned with 21.0 mg cytisinicline as the highest dose level. When the MTD was not reached at 21.0 mg, the studywas amended to evaluate doses up to 30.0 mg, as recommended by the DSMC. At this 30.0 mg dose, the stopping criteria of serious or severe AEs were still not met, but the DSMC recommended stopping the study since the frequency of gastrointestinal symptoms were approaching an MTD level. The results will be reviewed with the FDA to determine if further escalation beyond a single 30.0 mg dose will be required to define the MTD. This Phase-1 study is a requirement for our future NDA and marketing approval of cytisinicline. It fulfills an FDA requirement to evaluate potential safety issues in the event patients exceed a recommended single dose outside of a clinical trial setting. These results do not impact the intended dosing planned for future Phase 3 cytisinicline clinical trials which was informed by the Phase 2b ORCA-1 trial discussed below.

In June 2019, we announced positive top line results for the Phase 2b ORCA-1 trial and defined the dose selection of 3.0 mg, three times daily, or TID, for our Phase 3 development. ORCA-1 is the first in our ORCA (Ongoing Research of Cytisinicline for Addiction) Program that aims to evaluate the effectiveness of cytisinicline for smoking cessation, nicotine addiction therapy, and potential benefit in other indications.

ORCA-1 was initiated in October 2018 and evaluated 254 smokers in the United States. The trial evaluated both the 1.5 mg and 3.0 mg doses of cytisinicline on the standard declining titration schedule as well as a more simplified TID dosing schedule, both over 25 days. The trial was randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. Subjects were treated for 25 days, provided behavioral support, and followed up for an additional four weeks to assess smoking abstinence.

The primary endpoint in the study was the reduction in daily smoking, a self-reported measure. Three of the four cytisinicline treatment arms demonstrated a statistically significant reduction, $p<0.05$, compared to placebo. The fourth arm trended to significance ($p= 0.052$). Across all treatment arms, over the 25-day treatment period, subjects on cytisinicline experienced a 74-80% median reduction in the number of cigarettes smoked, compared to a 62% reduction in the placebo arms.

The secondary endpoint of the trial was a 4-week continuous abstinence rate, which is the relevant endpoint for regulatory approval. All cytisinicline treatment arms showed significant improvements in abstinence rates compared to the placebo arms. The most impressive results were observed in the 3.0 mg TID cytisinicline arm which demonstrated a 54% abstinence rate starting at week 4, compared to 16% for placebo ($p<0.0001$) and a continuous abstinence rate, weeks 5 through 8, of 30% for cytisinicline compared to 8% for placebo ($p= 0.005$). At week 4, all four cytisinicline arms demonstrated statistically significant ($p<0.05$) reductions in expired carbon monoxide, or CO, a biochemical measure of smoking activity. Expired CO levels had declined by a median of 71-80% in the cytisinicline treatment arms, compared to only 38% in the placebo arms. The greater reductions in expired CO levels for the cytisinicline arms versus placebo suggest that placebo-treated subjects may have over-reported their reduction in cigarettes smoked or overcompensated with greater inhalation while smoking fewer cigarettes.

Cytisinicline was well-tolerated with no serious AEs reported. The most commonly reported (>5%) AEs across all cytisinicline treatment arms versus placebo arms were abnormal dreams, insomnia, upper respiratory tract infections, and nausea. In the 3.0 mg TID treatment arm versus placebo arms, the most common AEs were abnormal dreams, insomnia, and constipation (each 6% vs 2%), upper respiratory tract infections (6% vs 14%), and nausea (6% vs 10%), respectively. Compliance with study treatment was greater than 94% across all arms.

Based on the results of the ORCA-1 trial, we have selected 3.0 mg TID for Phase 3 development. Overall, the 3.0 mg dose administered TID demonstrated the best overall safety and efficacy when compared to other doses and administrations studied in ORCA-1.

We presented the ORCA-1 results in September 2019 at the annual European meeting of the Society for Research on Nicotine and Tobacco (SRNT) held in Oslo, Norway. We also plan to discuss the trial's outcome with the FDA and finalize Phase 3 protocol details in the fourth quarter 2019.

We plan to initiate a Phase 3 trial in the first half of 2020 to evaluate the efficacy and safety of 3.0 mg TID of cytisinicline in smokers within the United States, subject to the availability of capital. The study plans to compare 3.0 mg TID of cytisinicline dosing versus placebo and will include behavioral support for all subjects. Co-primary endpoints of the study are an assessment of smoking abstinence during the last four weeks of 6-week and 12-week treatment periods, compared to similar placebo treatment periods. Secondary endpoints include smoking abstinence out to 24 weeks.

We are also considering potential clinical studies in users of e-cigarettes/vaping. This is an important area of focus given the youth vaping epidemic and the increasing number of vaping-related lung illnesses that have recently been reported. The number of e-cigarette users continues to grow and, according to data published in the Annals of Internal Medicine in 2018, there are a reported 10.8 million e-cigarette users in the United States alone. The National Institute on Drug Abuse, or NIDA, a division of the National Institutes of Health, or NIH, has tobacco/nicotine and vaping on their list of Drugs of Abuse. While e-cigarettes have been viewed as

safer than combustible cigarettes, the long-term safety of e-cigarettes is still unproven and may lead to a substitute form of nicotine addiction. Given the mechanism of action of cytisinicline, we believe it could be used to help address nicotine addiction for e-cigarette users. We are currently exploring non-dilutive funding sources as a way to potentially move forward with clinical studies in this setting.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We have never been profitable and have incurred operating losses in each year since inception. Our net loss was $13.2 million and $9.1 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $42.5 million, cash and cash equivalents balance of $7.4 million and a positive working capital balance of $4.5 million. During the nine months ended September 30, 2019, net cash used in operations was $11.8 million.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. We expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, and seek regulatory approval for, cytisinicline and add personnel necessary to operate as a public company with an advanced clinical candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate.

The accompanying financial results have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business. The financial results do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

License Agreements

Sopharma License and Supply Agreements

We are party to a license agreement, or the Sopharma License Agreement, and a supply agreement, or the Sopharma Supply Agreement, with Sopharma, AD, or Sopharma. Pursuant to the Sopharma License Agreement, we were granted access to all available manufacturing, efficacy and safety data related to cytisinicline, as well as a granted patent in several European countries related to new oral dosage forms of cytisinicline providing enhanced stability. Additional rights granted under the Sopharma License Agreement include the exclusive use of, and the right to sublicense, the trademark Tabex in all territories described in the Sopharma License Agreement. Under the Sopharma License Agreement, we agreed to pay a nonrefundable license fee. In addition, we agreed to make certain royalty payments equal to a mid-single digit percentage of all net sales of Tabex branded products in our territory during the term of the Sopharma License Agreement, including those sold by a third party pursuant to any sublicense which may be granted by us. To date, any amounts paid to Sopharma pursuant to the Sopharma License Agreement have been immaterial.

University of Bristol License Agreement

In July 2016, we entered into a license agreement with the University of Bristol, or the University of Bristol License Agreement. Under the University of Bristol License Agreement, we received exclusive and nonexclusive licenses from the University of Bristol to certain patent and technology rights resulting from research activities into cytisinicline and its derivatives, including a number of patent applications related to novel approaches to cytisinicline binding at the nicotinic receptor level.

In consideration of rights granted by the University of Bristol, we paid a nominal license fee and agreed to pay amounts of up to $3.2 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the University of Bristol License Agreement. Additionally, if we successfully commercialize any product candidates subject to the University of Bristol License Agreement, we are responsible for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products.

On January 22, 2018, we and the University of Bristol entered into an amendment to the University of Bristol License Agreement. Pursuant to the amended University of Bristol License Agreement we received exclusive rights for all human medicinal uses of cytisinicline across all therapeutic categories from the University of Bristol from research activities into cytisinicline and its derivatives. In consideration of rights granted by the amended University of Bristol License Agreement, we agreed to pay an initial amount of $37,500 upon the execution of the amended University of Bristol License Agreement, and additional amounts of up to $1.7 million, in the aggregate, tied to a financing milestone and to specific clinical development and commercialization milestones resulting from activities covered by the amended University of Bristol License Agreement, in addition to amounts under the original University of Bristol License Agreement of up to $3.2 million in the aggregate, tied to specific financing, development and commercialization milestones. Additionally, if we successfully commercialize any product candidate subject to the amended University of Bristol License Agreement or to the original University of Bristol License Agreement, we will be responsible, as provided in the original University of Bristol License Agreement, for royalty payments in the low-single digits and payments up to a percentage in the mid-teens of any sublicense income, subject to specified exceptions, based upon net sales of such licensed products. Up to September 30, 2019 we had paid the University of Bristol $125,000 pursuant to the University of Bristol License Agreement.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs for clinical trials, contract manufacturing, personnel costs, milestone payments to third parties, facilities, regulatory activities, preclinical studies and allocations of other R&D-related costs. External expenses for clinical trials include fees paid to clinical research organizations, clinical trial site costs and patient treatment costs.

We manage our clinical trials through contract research organizations and independent medical investigators at our sites and at hospitals and expect this practice to continue. Due to our ability to utilize resources across several projects, we do not record or maintain information regarding the indirect operating costs incurred for our research and development programs on a program-specific basis. In addition, we believe that allocating costs on the basis of time incurred by our employees does not accurately reflect the actual costs of a project.

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct our ongoing pre-clinical studies, and initiate new clinical trials and registration-enabling activities. The process of conducting clinical trials and pre-clinical studies necessary to obtain regulatory approval is costly and time consuming and we may never succeed in achieving marketing approval for cytisinicline. (See “Item 1A. Risk Factors—Risks Related to the Development of Our Product Candidate Cytisinicline.”)

Successful development of cytisinicline is highly uncertain and may not result in an approved product. We cannot estimate completion dates for development activities or when we might receive material net cash inflows from our R&D projects, if ever. We anticipate we will make determinations as to which markets, and therefore, which regulatory approvals, to pursue and how much funding to direct toward achieving regulatory approval in each market on an ongoing basis in response to our ability to enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, and ongoing assessments as to each future product candidate’s commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance its various programs.

Our projects or intended R&D activities may be subject to change from time to time as we evaluate results from completed studies, our R&D priorities and available resources.

General and Administrative Expenses

General and administrative, or G&A, expenses consist primarily of salaries and related costs for our personnel in executive, finance and accounting, corporate communications and other administrative functions, as well as consulting costs, including market research, business consulting, investor relations, human resources and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs.

Results of Operations

For the three and nine months ended September 30, 2019 and 2018

Research and development expenses

Our research and development expenses for our clinical development program for the three and nine months ended September 30, 2019 and 2018 are as follows (in thousands):

	Three months ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Clinical development programs:				
Cytisinicline	$ 1,824	$ 1,541	$ 7,911	$ 3,787
Total research and development expenses	**$ 1,824**	**$ 1,541**	**$ 7,911**	**$ 3,787**

Research and development expenses for the three and nine months ended September 30, 2019 increased to $1.8 million and $7.9 million, respectively, from $1.5 million and $3.8 million for the three and nine months ended September 30, 2018, respectively. The increase in 2019 as compared to the 2018 was primarily due to our ORCA-1 trial, a Phase 2b optimization study that was initiated in October 2018 and was completed in June 2019.

General and administrative expenses

Our general and administrative expenses for the three and nine months ended September 30, 2019 and 2018 are as follows (in thousands):

	Three months ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total general and administrative expenses	**$ 1,893**	**$ 1,753**	**$ 5,408**	**$ 5,317**

General and administrative expenses for the three and nine months ended September 30, 2019 were $1.9 million and $5.4 million, respectively, compared to $1.8 million and $5.3 million for the three and nine months ended September 30, 2018, respectively. The increase in 2019 as compared to 2018 was primarily due to initiation of market research activities related to cytisinicline and smoking cessation, which was partially offset by lower rent and facilities operating costs.

Liquidity and Capital Resources

We have incurred an accumulated deficit of $42.5 million through September 30, 2019 and we expect to incur substantial additional losses in the future as we operate our business and continue or expand our R&D activities and other operations. We have not generated any revenue from product sales to date, and we may not generate product sales revenue in the near future, if ever. As of September 30, 2019, we had a cash and cash equivalents balance of $7.4 million and a positive working capital balance of $4.5 million.

The financial results have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and liabilities and commitments in the normal course of business.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. There is no assurance that we will obtain financing from other sources. We have, thus far, financed our operations through payments from former collaborators and equity financings. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occur, our ability to achieve our development and commercialization goals would be adversely affected. In addition, we expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, and seek regulatory approval for, cytisinicline and add personnel necessary to operate as a public company with an advanced clinical candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidate. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, will have a negative impact on our financial condition and our ability to develop our product candidate.

The consolidated financial results do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should we be unable to continue as a going concern. Such adjustments could be material.

Lincoln Park Capital Equity Line

On September 14, 2017, we and Lincoln Park Capital Fund, LLC, or LPC, entered into a share and unit purchase agreement, or Purchase Agreement, pursuant to which we had the right to sell to LPC up to $11.0 million in shares of our common stock, par value $0.001 per share, subject to certain limitations and conditions set forth in the Purchase Agreement. On May 22, 2018 we obtained the requisite stockholder authorization to sell shares of our common stock to LPC in excess of 20% of our outstanding shares of common stock (as of the date we entered into the purchase agreement) in order to be able to sell to LPC the full amount remaining under the purchase agreement.

Pursuant to the Purchase Agreement, LPC initially purchased 32,895 of our units, or the Units, purchase price of $30.40 per unit, with each Unit consisting of (a) one share of our Common Stock and (b) one warrant to purchase one-quarter of a share of Common Stock at an exercise price of $34.96 per share, or Warrant. Each Warrant is exercisable six months following the issuance date until the date that is five years and six months after the issuance date and is subject to customary adjustments. The Warrants were issued only as part of the Units in the initial purchase of $1.0 million and no warrants shall be issued in connection with any other purchases of common stock under the Purchase Agreement.

After the initial purchase, if our stock price is above $1.00, as often as every other business day over the 30-month term of the Purchase Agreement, and up to an aggregate amount of an additional $10.0 million (subject to certain limitations) of shares of common stock, we have the right, from time to time, in our sole discretion and subject to certain conditions to direct LPC to purchase up to 8,000 shares of common stock with such amounts increasing as the closing sale price of our common stock as reported on The Nasdaq Capital Market increases. The purchase price of shares of common stock pursuant to the Purchase Agreement will be based on prevailing market prices of common stock at the time of sales without any fixed discount, and we will control the timing and amount of any sales of common stock to LPC. In addition, we may direct LPC to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below $20.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 12,351 shares of common stock; no cash proceeds were received from the issuance of these shares. The consideration of 12,352 shares of our common stock were fair valued based on the closing price of our common stock as at the transaction date and recognized as part of offering expenses.

During the three and nine months ended September 30, 2019, we offered and sold zero and 124,000, respectively, shares of our common stock pursuant to the Purchase Agreement with LPC for gross proceeds of approximately $0.4 million. Since entry into the Purchase Agreement, from September 14, 2017 through November 6, 2019, we offered and sold an aggregate of 557,378 shares of our common stock, including the 32,895 shares that were part of the initial purchase of Units. These aggregate sales resulted in gross proceeds to us of approximately $4.4 million and offering expenses of $0.5 million. As of November 6, 2019, shares of our common stock having an aggregate value of approximately $6.6 million remained available for sale under this offering program.

June 2018 Public Offering

On June 19, 2018, we completed an underwritten registered public offering, pursuant to which we sold 710,500 Class A Units at a price per unit of $4.00 and 9,158 Class B Units at a price per unit of $1,000.

Each Class A Unit consisted of one share of our common stock and a warrant to purchase one share of common stock.

Each Class B Unit consisted of one share of Series A Convertible Preferred Stock convertible at any time at the holder’s option into 250 shares of common stock and warrants to purchase 250 shares of common stock.

Each warrant was immediately exercisable, expires on the five year anniversary of the date of issuance and is exercisable at a price per share of common stock of $4.00. Additionally, subject to certain exceptions, if, after June 19, 2018, (i) the volume weighted average price of our common stock for each of any 30 consecutive trading days, or the Measurement Period, which Measurement Period commences on June 19, 2018, exceeds 300% of the exercise price (subject to adjustments for stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $500,000 per trading

day and (iii) certain other equity conditions are met, and subject to a beneficial ownership limitation, then we may call for cancellation of all or any portion of the warrants then outstanding

In addition, pursuant to the Underwriting Agreement we entered into with Ladenburg Thalmann & Co. Inc., or the Underwriter, on June 15, 2018, we granted the Underwriter a 45 day option, or the Overallotment Option, to purchase up to 450,000 additional shares of common stock and/or warrants to purchase up to 450,000 shares of Common Stock solely to cover over-allotments. The Overallotment Option was exercised in full on June 18, 2018.

We received net proceeds of approximately $12.2 million, after deducting underwriting discounts and commissions and offering expenses.

From June 19, 2018 to November 6, 2019, all 9,158 shares of the Series A Convertible Preferred Stock were converted into 2,289,500 shares of common stock and no shares of the Series A Convertible Preferred Stock remained outstanding.

From June 19, 2018 through November 6, 2019, 1,168,000 of the warrants issued in the June 2018 financing were exercised at a per unit price of $4.00, for proceeds of approximately $4.7 million and 2,282,000 warrants remained outstanding.

October 2018 Registered Direct Offering

On October 3, 2018, we completed a registered direct offering, pursuant to which we sold 1,789,258 shares of common stock at a price of $3.1445. We also issued to the investors in a concurrent private placement unregistered warrants to purchase up to 0.5 shares of common stock for each share purchased in the registered direct offering, with an exercise price of $3.1445 per share. The warrants were exercisable immediately upon issuance and will expire five years following the date of issuance.

The registered direct offering raised total gross proceeds of $5.6 million and after deducting approximately $0.6 million in placement agent fees and offering expenses, we received net proceeds of $5.0 million.

At The Market Offering Agreement with H.C. Wainwright & Co., LLC

On June 7, 2019, we entered into an At The Market Offering Agreement, or the Offering Agreement, with H.C. Wainwright & Co., LLC, as agent, or H.C. Wainwright, pursuant to which we may offer and sell, from time to time and at our election, through H.C. Wainwright, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $6.0 million.

Pursuant to the Offering Agreement, H.C. Wainwright may sell the shares our common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers’ transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. H.C. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares of common stock from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

We will pay H.C. Wainwright a commission rate equal to 3.0% of the aggregate gross proceeds from each sale of shares of common stock and have agreed to reimburse H.C. Wainwright for certain specified expenses in connection with entering into the Offering Agreement.

From June 7, 2019 to November 6, 2019, we did not offer any shares of our common stock for sale pursuant to the Offering Agreement. As of November 6, 2019, shares of our common stock having an aggregate value of approximately $6.0 million remained available for sale under the Offering Agreement.

Warrant Exercise Agreement

On May 30, 2019, we entered into a Warrant Exercise Agreement, or the Exercise Agreement, with Armistice Capital Master Fund, Ltd., or Armistice. Pursuant to the Exercise Agreement, Armistice exercised (i) outstanding warrants to purchase 270,313 shares of our common stock, par value $0.001 per share, with an exercise price of $3.1445 per share issued as part of the October 2018 financing and (ii) outstanding warrants to purchase 837,500 shares of our common stock with an exercise price of $4.00 per share issued as part of the June 2018 financing, for aggregate exercise proceeds to us of approximately $4.2 million, or, collectively, the Warrant Exercise.

As an inducement for the Warrant Exercise, we agreed to issue to Armistice a new warrant, exercisable for six years, to purchase up to 1,200,000 shares of our common stock at an exercise price of $4.50 per share. We also agreed to file a registration statement covering the resale of the New Warrant Shares. The New Warrant and New Warrant Shares were offered to Armistice in reliance upon the exemption provided by Rule 506 of Regulation D and Section 4(a)(2) of the Securities Act.

Under ASC 260, the fair value of the new warrants of $3.9 million was recognized into accumulated deficit.

Cash Flows

Cash Used in Operations

For the nine months ended September 30, 2019, net cash used in operating activities was $11.8 million compared to $7.1 million for the nine months ended September 30, 2018. The increase in cash used in operations in 2019 as compared to 2018 was primarily attributable to increased research and development expenses related to our ORCA-1 trial.

Cash Provided by Financing Activities

For the nine months ended September 30, 2019, net cash provided by financing activities was $4.6 million compared to $14.7 million for the nine months ended September 30, 2018. Net cash provided by financing activities in the nine months ended September 30, 2019 relates to proceeds received from warrant exercises and from our purchase agreement with LPC. Net cash provided by financing activities in the nine months ended September 30, 2018 relates to proceeds received from our June 2018 financing, our purchase agreement with LPC and warrant exercises.

Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2019 was $5.0 million compared to net cash used of $1.4 million for the nine months ended September 30, 2018. Net cash provided by investing activities in the nine months ended September 30, 2019 relates primarily to transactions involving marketable securities in the normal course of business. Net cash used in investing activities in the nine months ended September 30, 2018 relates primarily to the purchase of property and equipment.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet financing arrangements at September 30, 2019.

Commitments and Contingencies

We previously disclosed certain contractual obligations and contingencies and commitments relevant to us within the financial statements and Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 14, 2019. There have been no material changes to our "Contractual Obligations" table in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2018 Form 10-K. For more information regarding our current contingencies and commitments, see note 7 to the financial statements included above.

Material Changes in Financial Condition

(in thousands)	September 30, 2019	December 31, 2018
Total Assets	$ 11,492	$ 19,084
Total Liabilities	3,351	3,282
Total Equity	8,141	15,802

The decrease in assets at September 30, 2019 compared to December 31, 2018 is attributable to a decrease in cash, cash equivalents and short term investments as these assets have been used to fund operations.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed those estimates that we believe are critical and require the use of complex judgment in their application in our audited financial statements for the year ended December 31, 2018 in our Annual Report on Form 10-K filed with the SEC, on March 14, 2019. Since December 31, 2018, there have been no material changes to our critical accounting policies or the methodologies or assumptions we apply under them.

New Accounting Standards

See Note 2, "Accounting Policies," of the consolidated financial statements for information related to the adoption of new accounting standards in 2019 and the future adoption of recently issued accounting standards. The adoption of ASU No. 2016-02, Leases, had a significant impact on our accounting for our lease arrangements, particularly our current operating lease arrangements, as well as our disclosures.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that material information required to be disclosed in our periodic reports filed or submitted under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures are also designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act are accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure.

During the quarter ended September 30, 2019, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this report.

Changes in Internal Control Over Financial Reporting

We have not made any changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Risks Related to Our Business

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q and in the other periodic and current reports and other documents we file with the Securities and Exchange Commission, before deciding to invest in our common stock. If any of the following risks materialize, our business, financial condition, results of operation and future prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline and you could lose all or part of your investment. This list is not exhaustive and the order of presentation does not reflect management's determination of priority or likelihood.

Risks Related to Our Financial Condition and Capital Requirements

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidate.

Substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is uncertain and dependent on our ability to obtain additional financing. We have expended and continue to expend substantial funds in connection with our product development, clinical trial and regulatory approval activities.

In addition, we expect to incur significant expenses and increasing operating losses for at least the next several years as we continue our clinical development of, and seek regulatory approval for, cytisinicline and add personnel necessary to operate as a public company with an advanced clinical candidate. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Our current resources are insufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidate. The current financing environment in the United States, particularly for biotechnology companies like us, is exceptionally challenging and we can provide no assurances as to when such environment will improve. For these reasons, among others, we cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders. If adequate financing is not available, we may need to continue to reduce or eliminate our expenditures for research and development of cytisinicline, and may be required to suspend development of cytisinicline. Our actual capital requirements will depend on numerous factors, including:

- our commercialization activities and arrangements;
- the progress and results of our research and development programs;
- the progress of our non-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals for our product candidate;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights with respect to our intellectual property;
- the effect of competing technological and market developments;

- the effect of changes and developments in our existing collaborative, licensing and other relationships; and
- the terms of any new collaborative, licensing, commercialization and other arrangements that we may establish.

We may not be able to secure sufficient financing on acceptable terms, or at all. Without additional funds, we may be forced to delay, scale back or eliminate some of our research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occur, our ability to achieve our development and commercialization goals would be adversely affected.

We have incurred losses since inception, have a limited operating history on which to assess our business and anticipate that we will continue to incur losses for the foreseeable future. We have never had any products available for commercial sale and we may never achieve or sustain profitability.

We are a clinical development-stage specialty pharmaceutical company with a limited operating history, are not profitable,have incurred losses in each year since our inception and do not expect to become profitable in the foreseeable future. We have never had any products available for commercial sale, and we have not generated any revenue from product sales, nor do we anticipate that we will generate revenue from product sales in the near future.

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have devoted substantially all of our financial resources to identify, acquire, and develop cytisinicline, including providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and convertible promissory notes. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or grants.

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

- continue the clinical development of cytisinicline;
- advance cytisinicline development into larger, more expensive clinical trials;
- initiate additional non-clinical, clinical, or other trials or studies for cytisinicline;
- seek to attract and retain skilled personnel;
- undertake the manufacturing of cytisinicline or increase volumes manufactured by third parties;
- seek regulatory and marketing approvals and reimbursement for cytisinicline;
- make milestone, royalty or other payments under third-party license and/or supply agreements;
- establish a sales, marketing, and distribution infrastructure to commercialize any product for which we may obtain marketing approval and market for ourselves;
- seek to discover, identify, assess, acquire, and/or develop other product candidates;
- seek to establish, maintain, protect, and expand our intellectual property portfolio; and
- experience any delays or encounter issues with the development and potential for regulatory approval of cytisinicline such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies, or supportive studies necessary to support marketing approval.

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

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

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

- completing research and development of cytisinicline;
- obtaining regulatory and marketing approvals for cytisinicline;
- manufacturing product and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, satisfy regulatory requirements and meet our supply needs in sufficient quantities to satisfy market demand for cytisinicline, if approved;
- marketing, launching and commercializing any product for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- obtaining reimbursement or pricing for cytisinicline that supports profitability;
- gaining market acceptance of cytisinicline as a treatment option;
- addressing any competing products, including the potential for generic cytisinicline products;
- protecting and enforcing our intellectual property rights, if any, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, commercialization, or other arrangements into which we may enter; and
- attracting, hiring, and retaining qualified personnel.

Even if a product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing that candidate. Additionally, if we are not able to generate sufficient revenue from the sale of any approved products to cover our operating costs, we may never become profitable. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidate may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidate in those markets.

We are dependent upon a single company for the manufacture and supply of cytisinicline.

Our single product candidate, cytisinicline, has been in-licensed from a third party. We are required to continue to contract with Sopharma AD, or Sopharma, to continue our development of, and potential commercialization of, cytisinicline pursuant to a supply agreement with Sopharma. If the supply agreement with Sopharma is terminated, we will need to develop or acquire alternative supply and manufacturing capabilities for cytisinicline, which we may not be able to do on commercially viable terms or at all.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Capital Market. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costly. In addition, it may be difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

Recently enacted comprehensive tax reform bills could increase our tax burden and adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation, the Tax Cuts and Jobs Act of 2017, that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate.

In addition, beginning in 2022, the recently enacted tax legislation will require research and experimental expenditures to be capitalized and amortized ratably over a five-year period. Any such expenditures attributable to research conducted outside the U.S. must be capitalized and amortized over a 15-year period.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the recently enacted federal tax law.

Risks Related to the Development of Our Product Candidate Cytisinicline

Cytisinicline is currently our sole product candidate and there is no guarantee that we will be able to successfully develop and commercialize cytisinicline.

We are currently dependent on the potential development of a single product candidate, cytisinicline. We are still developing our sole product candidate, and cytisinicline cannot be marketed or sold in the United States or in foreign markets until regulatory approval has been obtained from the U.S. Food and Drug Administration, or the FDA, or applicable foreign regulatory agencies. The process of obtaining regulatory approval is expensive and time consuming. The FDA and foreign regulatory authorities may never approve cytisinicline for sale and marketing, and even if cytisinicline is ultimately approved, regulatory approval may be delayed or limited in the United States or in other jurisdictions. Even if we are authorized to sell and market cytisinicline in one or more markets, there is no assurance that we will be able to successfully market cytisinicline or that cytisinicline will achieve market acceptance sufficient to generate profits. If we are unable to successfully develop and commercialize cytisinicline due to failure to obtain regulatory approval for cytisinicline, to successfully market cytisinicline, to generate profits from the sale of cytisinicline, or due to other risk factors outlined in this report, it would have material adverse effects on our business, financial condition, and results of operations as cytisinicline is currently our sole product candidate.

Results of earlier clinical trials of cytisinicline are not necessarily predictive of future results, and any advances of cytisinicline into clinical trials may not have favorable results or receive regulatory approval.

Even if our clinical trials are completed as planned, we cannot be certain that their results will be consistent with the results of the earlier clinical trials of cytisinicline. Positive results in non-clinical testing and past clinical trials with respect to the safety and efficacy of cytisinicline do not ensure that results from subsequent clinical trials will also be positive, and we cannot be sure that the results of subsequent clinical trials will replicate the results of prior clinical trials and non-clinical testing. Any such failure may cause us to abandon cytisinicline, which would negatively affect our ability to generate any product revenues.

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

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

- delays in reaching agreement on acceptable terms with clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays in recruiting qualified patients in its clinical trials;
- failure by clinical sites, CROs or other third parties to adhere to clinical trial requirements;
- failure by clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- patients terminating enrollment in our clinical trials;
- adverse events or tolerability issues significant enough for the FDA or other regulatory agencies to put any or all clinical trials on hold;

- inability to generate satisfactory non-clinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- animal toxicology issues significant enough for the FDA or other regulatory agencies to disallow investigation in humans;
- occurrence of adverse events associated with our product candidate;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of cytisinicline;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in ongoing or other planned indications for cytisinicline; and
- delays in the manufacture or packaging of sufficient quantities of cytisinicline for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for cytisinicline could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to cytisinicline, we may need to conduct additional non-clinical trials or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize cytisinicline and may harm our business and results of operations.

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

Undesirable side effects caused by cytisinicline could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities.

Additionally, even if cytisinicline receives marketing approval, and we or others later identify undesirable side effects caused by cytisinicline, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of cytisinicline;
- regulatory authorities may require additional warnings on the cytisinicline label;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

Our product development program may not uncover all possible adverse events that patients who take cytisinicline or our other product candidates may experience. The number of subjects exposed to cytisinicline or our other product candidates and the average exposure time in the clinical development program may be inadequate to detect rare adverse events, or chance findings, that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. We cannot be fully assured that rare and severe side effects of cytisinicline will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to cytisinicline or over a significantly longer period of time. If such safety problems occur or are identified after cytisinicline reaches the market in the United States, or if such safety problems occur or are identified in foreign markets where cytisinicline is currently marketed, the FDA may require that we amend the labeling of cytisinicline or recall it, or may even withdraw approval for cytisinicline.

If the use or misuse of cytisinicline harms patients, or is perceived to harm patients even when such harm is unrelated to cytisinicline, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting

from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

The use or misuse of cytisinicline in clinical trials and the sale of cytisinicline if marketing approval is obtained, exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product. There is a risk that cytisinicline may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, during the course of treatment, patients may suffer adverse events for reasons that may be related to cytisinicline. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market cytisinicline, if any, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to cytisinicline, an investigation into such circumstance may be time-consuming or inconclusive. Such investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals cytisinicline receives or maintains. As a result, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we obtain marketing approval for cytisinicline, we will need to expand our insurance coverage to include the sale of commercial products. We cannot know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage.

Where we have provided indemnities in favor of third parties under our agreements with them, there is a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may also bring a product liability claim against us alleging that cytisinicline causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- an inability to commercialize, or if commercialized, a decreased demand for, cytisinicline;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenue, if any;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- increased product liability insurance rates, or inability to maintain insurance coverage in the future on acceptable terms, if at all;
- diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations.

The development of our product candidate is dependent upon securing sufficient quantities of cytisinicline from the Laburnum anagyroides plant, which grows outside of the United States in a limited number of locations.

The therapeutic component of our product candidate, cytisinicline, is derived from the seeds of the *Laburnum anagyroides* plant, which grows in the mountains of Southern Europe. We currently secure cytisinicline exclusively from Sopharma, a Bulgarian third-party supplier. Our current supply agreement with Sopharma expires on July 28, 2037, unless extended by mutual agreement of us and Sopharma. There can be no assurances that *Laburnum anagyroides* will continue to grow in sufficient quantities to meet commercial supply requirements or that the countries from which we can secure *Laburnum anagyroides* will continue to allow the exportation of cytisinicline. Sopharma currently has planted approximately 1,000 acres of *Laburnum* trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria and is in the process of planting another 750 acres. Sopharma plans to plant additional trees to manage supply for major markets. Each tree takes approximately four to six years to reach maturity for harvesting and has a productive life expectancy of 20 to 25 years. Although Sopharma has plans to plant significant numbers of additional trees, there is no

guarantee that they will do so or thatthe trees will produce the anticipated yield of cytisinicline. In the event we are no longer able to obtain cytisinicline from Sopharma, or in sufficient quantities, we may not be able to produce our proposed products and our business will be adversely affected.

Our business may be negatively affected by weather conditions and the availability of natural resources, as well as by climate change.

In recent years, extreme weather events and changing weather patterns such as storms, flooding, drought, and temperature changes appear to have become more common. The production of cytisinicline from the *Laburnum anagyroides* plant depends on the availability of natural resources, including sufficient rainfall. Our exclusive supplier of cytisinicline, Sopharma, could be adversely affected if it experiences a shortage of fresh water due to droughts or if it experiences other adverse weather conditions. As a result of such events, we could experience cytisinicline shortages from Sopharma, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the manufacturing and other operations of Sopharma are located near earthquake fault lines in Sofia, Bulgaria. In the event of a major earthquake, we could experience business interruptions from the disruption of our cytisinicline supplies, which could have a material adverse effect on our business, financial condition and results of operations.

We may conduct clinical trials internationally, which may trigger additional risks.

If we decide to conduct clinical trials in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. Failure to meet such regulatory requirements could delay our clinical trials, the approval, if any, of cytisinicline by the FDA or other regulatory authorities, or the commercialization of cytisinicline, or result in higher costs or deprive us of potential product revenues.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with some programs or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Our risk of delay in product development is increased if the United States government is fully or partially shut down due to lack of continuity in funding.

Our business operations, and particularly the timing of the outcome of review of our clinical development plans for cytisinincline, are directly and indirectly affected by the operations of the United States government, including but not limited to the FDA. Any interruption in the continuity of funding of all or a part of government activities could have a significant negative effect on our business, including the timing of any proposed interactions with the FDA related to clinical development advice or ultimately any NDA filing. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the United States government has had shut downs. We cannot predict the likelihood, duration, impact, or timing of any future shutdown. There can be no assurance that if such shutdown(s) were to occur in the future, adequate funds would be available to the FDA and other U.S. government agencies to allow them to continue their activities uninterrupted. Even when funding is restored following one or more shutdowns, we cannot predict the ongoing impact of such shutdowns on our business, or the degree to which funding would be restored to the FDA or other agencies having an impact on our business.

Risks Related to Regulatory Approval of Cytisinicline and Other Legal ComplianceMatters

If we do not obtain the necessary regulatory approvals in the United States and/or other countries, we will not be able to sell cytisinicline.

We will need approval from the FDA to commercialize cytisinicline in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize cytisinicline in those jurisdictions. In order to obtain FDA approval of cytisinicline, we must submit an NDA to the FDA, demonstrating that cytisinicline is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including completion of clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depending upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of cytisinicline or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in data that the FDA considers safe and effective for the proposed indications of cytisinicline. The FDA has substantial discretion in the product approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory approval for cytisinicline. Failure to obtain approval from the FDA or comparable regulatory authorities in foreign jurisdictions to commercialize cytisinicline will leave us without saleable products and therefore without any source of revenues. In addition, the FDA may require us to conduct additional clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product or permit continued marketing, if previously approved. If conditional marketing approval is obtained, the results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. In foreign jurisdictions, the regulatory approval processes generally include the same or similar risks as those associated with the FDA approval procedures described above. We cannot be certain that we will receive the approvals necessary to commercialize cytisinicline for sale either within or outside the United States.

Even if we obtain regulatory approval for cytisinicline, we will remain subject to ongoing regulatory requirements in connection with the sale and distribution of cytisinicline.

Even if cytisinicline is approved by the FDA or comparable foreign regulatory authorities, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and the requirements of comparable foreign regulatory authorities. Compliance with such regulatory requirements will likely be costly and the failure to comply would likely result in penalties, up to and including, the loss of such approvals from the FDA or comparable foreign regulatory authorities.

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

Ongoing post-approval monitoring and clinical trial obligations may be costly to us and the failure to meet such obligations may result in the withdrawal of such approvals.

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

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the

market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or the Healthcare Reform Law, requires manufacturers of products, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

Healthcare legislative and executive reform measures may have a material adverse effect on our business, financial condition or results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Healthcare Reform Law was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Healthcare Reform Law, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted, or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription products, and promotes a new Medicare Part D coverage gap discount program.

On January 20, 2017, President Donald Trump issued an Executive Order to initiate the repeal of the Healthcare Reform Law and we anticipate that additional state and federal healthcare measures under the Trump administration could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for cytisinicline, or additional pricing pressures. Currently, the Healthcare Reform Law provides coverage for smoking cessation-related activities, including two counseling attempts for smoking cessation per year and medications for smoking cessation. If these provisions are repealed, in whole or in part, our business, financial condition, or results of operations could be negatively affected.

The United Kingdom is currently a member state of the European Union. However, the United Kingdom has signaled its intention to withdraw from the European Union (commonly known as Brexit). If Brexit, which is likely to occur in 2019, does occur, the United Kingdom will no longer be a member state within the European Union. Since a significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union, Brexit could materially change the regulatory framework applicable to the approval of cytisinicline, which could have a material adverse effect on us and our operations. Brexit may also result in other significant regulatory and legislative changes in the United Kingdom, which could, for example, affect the pricing of pharmaceutical products in the United Kingdom, which could in turn result in diminished performance for us. Even if the substance of regulatory changes resulting from Brexit does not have a significant impact on our operations, it is reasonable to expect that we would incur potentially significant costs in connection with complying with any new regulations. Further, the European Medicines Agency is currently located in the United Kingdom. It is possible that Brexit would result in the relocation of the European Medicines Agency or disruption to the European Medicines Agency's review process, either of which could have an adverse effect on our operations in the United Kingdom and the European Union.

Brexit may also have adverse effects on potential customers and collaborators of ours, which could indirectly have an adverse effect on us.

Our ability to obtain services, reimbursement or funding may be impacted by possible reductions in federal spending in the United States as well as globally.

U.S. federal government agencies currently face potentially significant spending reductions. Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021 triggered automatic cuts to most federal programs. These cuts would include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was enacted on January 1, 2013, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. The full impact on our business of these automatic cuts is uncertain.

If government spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop . Any reductions in government spending in countries outside the United States may also impact us negatively, such as by limiting the functioning of international regulatory agencies in countries outside the United States or by eliminating programs on which we may rely.

Risks Related to our Business Operations

It is difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

To date our business activities have been focused primarily on the development and regulatory approval of cytisinicline and its various alternative forms. Although we have not generated revenue to date, we expect that, after any regulatory approval, any receipt of revenue will be attributable to sales of cytisinicline, primarily in the United States, the European Union (including the United Kingdom) and Asia. Because we devote substantially all of our resources to the development of cytisinicline and rely on cytisinicline as our sole source of potential revenue for the foreseeable future, any factors that negatively impact this product, or result in decreasing product sales, would materially and adversely affect our business, financial condition and results of operations.

Our future success depends in part on our ability to attract, retain, and motivate other qualified personnel.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our development and commercialization efforts for our existing and future product candidates. We expect to need additional scientific, technical, operational, financial and other personnel. Our success depends on our continued ability to attract, retain and motivate highly qualified personnel, such as management, clinical and preclinical personnel, including our executive officers Richard Stewart, John Bencich, Cindy Jacobs, Anthony Clarke and Jaime Xinos. In addition, although we have entered into employment agreements with each of Mr. Stewart, Mr. Bencich, Dr. Jacobs, Dr. Clarke and Ms. Xinos, such agreements permit those executives to terminate their employment with us at any time, subject to providing us with advance written notice.

We may not be able to attract and retain personnel on acceptable terms, if at all, given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of cytisinicline may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of our current personnel may impede the progress of our research, development, and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

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

We may need to expand our organization, which may require us to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in its infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Expanded growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

In the future, we may invest in the development of additional indications for cytisinicline. If we invest in and are unsuccessful in developing additional indications for cytisinicline, our business, financial condition and results of operations may be adversely affected.

In the future, we may invest in the research and development of new indications for cytisinicline to address nicotine addictions associated with the use of electronic cigarette, or vaping, products. Given their recent introduction, the use of vaping products is not fully understood which may increase the risk of failure in this area. The development of additional indications for cytisinicline is highly uncertain. During the research and development cycle, we may expend significant time and resources on developing additional indications without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of additional indications, and failure can occur at any point in the process, including late in the process after substantial investment. Further, any new indications may not be accepted by physicians and the medical community at large, and competitors may develop and market equivalent or superior products. Failure to launch commercially

successful new indications for cytisinicline after significant investment could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We expect to continue to rely on third parties to manufacture cytisinicline for use in clinical trials, and we intend to exclusively rely on Sopharma to produce and process cytisinicline, if approved. Our commercialization of cytisinicline could be stopped, delayed or made less profitable if Sopharma fails to obtain approval of government regulators, fails to provide us with sufficient quantities of product, or fails to do so at acceptable quality levels or prices.

We do not currently have nor do we currently plan to develop the infrastructure or capability internally to manufacture our clinical supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture cytisinicline on a clinical or commercial scale. We currently exclusively rely on Sopharma to manufacture cytisinicline for use in clinical trials and plan to continue relying on Sopharma to manufacture cytisinicline on a commercial scale, if approved.

Our reliance on Sopharma exposes us to the following additional risks:

- Sopharma might be unable to timely manufacture cytisinicline or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- we may be unable to identify manufacturers other than Sopharma on acceptable terms or at all;
- Sopharma may not be able to execute our manufacturing procedures appropriately;
- Sopharma may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- Sopharma is or will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with Current Good Manufacturing Practices, or cGMPs, and other government regulations and corresponding foreign standards. We do not have control over Sopharma's compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by Sopharma in the manufacturing process for cytisinicline;
- we do not own the intellectual property rights to cytisinicline, and Sopharma could license such rights to third parties or begin supplying other third parties with cytisinicline; and
- Sopharma could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of cytisinicline by the FDA or the commercialization of cytisinicline or result in higher costs or deprive us of potential product revenue.

We rely on third party contract manufacturing organizations, or CMOs, to package the cytisinicline used in our clinical trials. If any of these CMO's fail to timely deliver supplies needed then our clinical studies could be delayed materially. Third-party manufacturers may fail to perform under their contractual obligations, or may fail to deliver the required commercial product on a timely basis and at commercially reasonable prices. If we are required to identify and qualify an alternate manufacturer, we may be forced to delay or suspend our clinical trials. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in the supply of cytisinicline or in the Sopharma manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of cytisinicline will not occur in the future. Additionally, Sopharma may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or political instability in the countries in which Sopharma conducts its operations. If Sopharma were to encounter any of these difficulties, or otherwise fail to comply with its contractual obligations, our ability to provide our product candidate to patients in clinical trials could be delayed or suspended. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Similar political instability could also harm the commercial production and supply of cytisinicline in the event that cytisinicline is ultimately approved for commercial sale.

We rely on third parties to conduct our clinical trials and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize cytisinicline and our business could be substantially harmed.

We plan to rely upon third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we or any of our CROs or vendors fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be assured that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process.

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

We may not be able to establish or maintain the third-party relationships that are necessary to develop or potentially commercialize cytisinicline.

Our business plan relies heavily on third party collaborators, partners, licensees, clinical research organizations, clinical investigators, vendors or other third parties to support our research and development efforts and to conduct clinical trials for cytisinicline. We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, these third parties on a commercially reasonable basis, if at all. If we fail to establish or maintain such third-party relationships as anticipated, our business could be adversely affected.

We may be unable to realize the potential benefits of any collaborations which we may enter into with other companies for the development and commercialization of cytisinicline.

We may enter into a collaboration with third parties concerning the development and/or commercialization of cytisinicline; however, there is no guarantee that any such collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of cytisinicline;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to cytisinicline, or other potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaborators may cease to devote resources to the development or commercialization of cytisinicline if the collaborators view cytisinicline as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of cytisinicline, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- the collaborations may not result in us achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of cytisinicline.

As a result, a collaboration may not result in the successful development or commercialization of cytisinicline.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Cytisinicline

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.

The development and commercialization of new products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to cytisinicline and the other product candidates that we may seek to develop or commercialize in the future. We are aware that many companies have therapeutics marketed or in development for smoking cessation, including, Pfizer Inc., GlaxoSmithKline Plc, Merck & Co., Novartis, Pharmacia Polonica, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, zpharm, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm, Adamed, Aflofarm, Axsome, Smoke Free Therapeutics, Antidote Therapeutics and others.

Many of our competitors have substantially greater financial, name recognition, manufacturing, marketing, research, technical and other resources than us. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Further, our competitors may develop new products that are safer, more effective or more cost-efficient than cytisinicline. Large pharmaceutical companies in particular have extensive expertise in non-clinical and clinical testing and in obtaining regulatory approvals for products. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure of cytisinicline to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

The commercial success of cytisinicline will depend upon the degree of market acceptance by physicians, patients, third-partypayors, and others in the medical community. Failure to obtain or maintain adequate reimbursement or insurance coverage for products, if any, could limit our ability to market cytisinicline and decrease our ability to generate revenue.

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of cytisinicline will depend in part on the healthcare providers, patients, and third-party payors accepting cytisinicline as medically useful, cost-effective, and safe. Cytisinicline may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of cytisinicline will depend on a number of factors, including but not limited to:

- the safety and efficacy, if any, of cytisinicline as demonstrated in clinical trials and potential advantages over competing treatments, if any;
- the clinical indications for which approval is granted, if any, including any limitations or warnings contained in cytisinicline's approved labeling;
- the cost of treatment;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend the product to patients based on such risks and benefits;
- the marketing, sales and distribution support for cytisinicline;
- the publicity concerning cytisinicline or competing products and treatments;
- the pricing and availability of third-party insurance coverage and reimbursement;
- negative perceptions or experiences with our competitor's products may be ascribed to cytisinicline; and
- availability of cytisinicline from other suppliers and/or distributors.

Even if cytisinicline displays a favorable efficacy and safety profile upon approval, market acceptance of cytisinicline remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of cytisinicline, if any, may require significant investment and resources and may never be successful. Additionally, third-party payors, including governmental and private insurers, may also encourage the use of generic products instead of cytisinicline, or a generic version of cytisinicline, which require a prescription. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other healthcare providers, we will not be able to generate sufficient revenue to become or remain profitable.

The pricing, coverage, and reimbursement of cytisinicline, if any, must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford treatments. Sales of cytisinicline, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of cytisinicline will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide cytisinicline for free or we may not be able to successfully commercialize cytisinicline.

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

Outside the United States, selling operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes.

The downward pressure on healthcare costs in general, particularly prescription products has and is expected to continue to increase in the future. As a result, profitability of cytisinicline, if any, may be more difficult to achieve even if regulatory approval is received.

Sopharma may breach its supply agreement with us and sell cytisinicline into our territories or permit third parties to export cytisinicline into our territories and negatively affect our commercialization efforts of our products in our territories.

We are currently dependent on the exclusivity provisions of our supply agreement with Sopharma to conduct our business and to prevent Sopharma from competing, directly and indirectly, with us in the United States and Western Europe. If Sopharma were to breach the exclusivity provisions of the supply agreement with us and sell or distribute cytisinicline directly into our territories or permit third parties to export cytisinicline into our territories, among other things, the increase in competition within our anticipated markets could have a material adverse effect on our business, results of operations and financial condition.

The illegal distribution and sale by third parties of counterfeit versions of cytisinicline, stolen products, or alternative third party distribution and sale of cytisinicline could have a negative impact on our financial performance or reputation.

Cytisinicline is not patentable in the United States as it is a naturally occurring substance. As such, third parties are able to manufacture, sell or distribute cytisinicline without royalties or other payments to us and compete with our products in the United States and potentially worldwide and negatively impact our commercialization efforts of our products. We are aware of additional cytisinicline products approved in several European countries and we may not be able to block other third parties from launching generic versions of cytisinicline. Third parties may also sell or distribute cytisinicline as an herbal or homeopathic product. Other than regulatory exclusivity or other limitations, there may be little to nothing to stop these third parties from manufacturing, selling or distributing cytisinicline. Because we have no ability to set rigorous safety standards or control processes over third party manufacturers, sellers or distributors of cytisinicline, excluding Sopharma, these formulations of cytisinicline may be unsafe or cause adverse effects to patients and negatively impact the reputation of cytisinicline as a safe and effective smoking cessation aid.

Third parties could illegally distribute and sell counterfeit versions of cytisinicline, especially on online marketplaces, which do not meet the rigorous manufacturing and testing standards under cGMP. Counterfeit products are frequently unsafe or ineffective, and may even be life-threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the active pharmaceutical ingredient or no active pharmaceutical ingredients at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version.

Reports of adverse reactions to counterfeit products, increased levels of counterfeiting, or unsafe cytisinicline products could materially affect patient confidence in our cytisinicline product. It is possible that adverse events caused by unsafe counterfeit or other non-Achieve cytisinicline products will mistakenly be attributed to our cytisinicline product. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels could adversely impact patient safety, our reputation, and our business. Public loss of confidence in the integrity in cytisinicline as a result of counterfeiting, theft, or improper manufacturing processes could have a material adverse effect on our business, results of operations, and financial condition.

It is illegal to sell unapproved prescription medicines in the United States. Sopharma's cytisinicline brand, Tabex, is currently approved for sale in certain Central and Eastern European countries. Cytisinicline has not yet received a marketing approval from the FDA or the European Medicines Agency, and we intend to conduct the requisite clinical trials to obtain approval for the marketing of cytisinicline in the United States and in Europe. We are aware that products purporting to be Tabex are available, via third party internet sites, for importation in the United States and other global markets. We have no control over the authenticity of products purchased through these sites, which may be counterfeit or sourced from distributors in Central and Eastern Europe without authorization to sell into the United States or European Union.

We may attempt to form collaborations in the future with respect to cytisinicline, but we may not be able to do so, which may cause us to alter our development and commercialization plans.

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for cytisinicline on terms that are acceptable to us, or at all. This may be because cytisinicline may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, or cytisinicline's patent protection insufficient, and/or third parties may not view cytisinicline as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaborators and entering into agreements todevelop and/or commercialize cytisinicline could delay the development or commercialization of cytisinicline, which may reduce our competitiveness even if we reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidate cytisinicline or bring it to market and our business may be materially and adversely affected.

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

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

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

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

Risks Related to our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to cytisinicline, product compounds and processes for our development pipeline through acquisitions and in-licenses.

Presently, we have rights to the intellectual property through trade secrets, licenses from third parties and patent applications that we own. Our product candidate may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

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

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

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

We are currently developing cytisinicline for smoking cessation. Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. We are not aware of any patents or patent applications that would prevent the development, manufacture or marketing of cytisinicline for smoking cessation.

We are aware of U.S. and foreign patents and pending patent applications owned by third parties that cover certain other therapeutic uses of cytisinicline. We are currently monitoring these patents and patent applications. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications for these certain additional therapeutic uses. If any third-party patents or patent applications cover our product candidates or technologies in other therapeutic uses, we may not be free to manufacture or market our product candidates for additional therapeutic uses, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

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

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

We intend to rely on patent rights for certain aspects of our product candidates and certain future product candidates. If we are unable to obtain or maintain an adequate proprietary position from this approach, we may not be able to compete effectively in our markets.

Although we rely or will rely primarily on trade secret protection as part of our intellectual property rights strategies, we also intend to rely on patent rights to protect certain aspects of our technologies and upon the patent rights of third parties from which we license certain of our technologies.

We have sought to protect our proprietary position by filing patent applications in the United Kingdom, United States and certain other countries around the world related to future product candidates. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or at all. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patent applications or our patents (once issued) have been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our future product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our future product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

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

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

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

Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the U.S. Patent and Trademark Office, or the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

In a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc*., the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Cytisinicline is a naturally-occurring product and is not patentable. Our intellectual property strategy involves novel formulations of cytisinicline and there is no guarantee that such patents will be issued or if issued, will be broad enough to prevent competitors from developing competing cytisinicline products. Although we do not believe that any patents that may issue from our pending patent applications directed at our product candidate, if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

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

Risks Related to Our Common Stock

The price for our common stock is volatile.

The market prices for our common stock and thatof early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to raise additional capital, the terms of such capital, and our ability to continue as a going concern;
- the ability of us or our partners to develop cytisinicline and other product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- the ability of us or our partners to obtain regulatory approvals for cytisinicline or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure to maintain our existing third-party license, manufacturing and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;

- if securities or industry analysts do not publish research or reports about us, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock us or our stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of healthcare payment systems;
- period-to-period fluctuations in our financial results; and
- tweets or other social media posts related to our market and industry.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. An increase in the market price of our common stock, which is uncertain and unpredictable, may be the sole source of gain from an investment in our common stock. An investment in our common stock may not be appropriate for investors who require dividend income. We have never declared or paid cash dividends on our capital stock and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for stockholders for the foreseeable future. Accordingly, an investment in our common stock may not be appropriate for investors who require dividend income or investors who are not prepared to bear a significant risk of losses from such an investment.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, including in circumstances where such declines occur in close proximity to the announcement of clinical trial results. Additionally, our stock price and those of other biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Because our recent merger resulted in an ownership change under Section 382 of the U.S. Internal Revenue Code for OncoGenex, pre-merger net operating loss carryforwards and certain other tax attributes are now subject to limitations.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the U.S. Internal Revenue Code, the corporation's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Our recent merger involving OncoGenex and Achieve Life Sciences, Inc. resulted in an ownership change for OncoGenex and, accordingly, OncoGenex's net operating loss carryforwards and certain other tax attributes will be subject to limitations on their use after the merger. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Anti-takeover provisions under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The sale of additional shares of common stock pursuant to our existing equity sale agreements may cause the price of our common stock to decline and result in dilution to our existing stockholders.

Pursuant to our purchase agreement with LPC, we have the right, from time to time, in our sole discretion and subject to certain conditions, to direct LPC to purchase additional shares of common stock having an aggregate value of $10.0 million and we have exercised this right. We have directed LPC to purchase additional shares and may further direct LPC to purchase additional shares as often as every business day over the 30-month term of the Purchase Agreement in increments of up to 80,000 shares of common stock, with such amounts increasing as the closing sale price of our common stock increases. The purchase price of shares of common stock pursuant to the Purchase Agreement have been and will be based on prevailing market prices of common stock at the time of sale without any fixed discount, and we have controlled and will control the timing and amount of any sales of common stock to LPC. In addition, we have directed and we may direct LPC in the future to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below $2.00 per share.

Pursuant to the terms of the Offering Agreement, we may offer and sell, from time to time through H.C. Wainwright, shares of our common stock having an aggregate offering price of up to $6.0 million. We will control the timing and amount of any sales of common stock under the Offering Agreement. Under the terms of the Offering Agreement, H.C. Wainwright may sell the shares our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers' transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with H.C. Wainwright. We have not offered any shares of our common stock for sale pursuant to the Offering Agreement, but could do so in the future.

The sale of additional shares of our common stock pursuant to our purchase agreement with LPC or the Offering Agreement has or will have a dilutive impact on our existing stockholders. Sales by us to LPC or by H.C. Wainwright under the Offering Agreement could cause the market price of our common stock to decline significantly. Sales of our common stock under the purchase agreement or the Offering Agreement, or the perception that such sales will occur, could also encourage short sales by third parties, which could contribute to the further decline of our stock price. Additionally, the sale of a substantial number of shares of our common stock under the purchase agreement or the Offering Agreement, or the perception that such sales will occur, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish.

If we raise additional capital, the terms of the financing transactions may cause dilution to existing stockholders or contain terms that are not favorable to us.

In the future, we plan to raise additional capital through private placements or public offerings of our equity or debt securities. We cannot be certain that additional funding will be available on acceptable terms, if at all. To the extent that we raise additional financing by issuing equity securities, we may do so at a price per share that represents a discount to the then-current per share trading price of our common stock and our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a "smaller reporting company" as defined in the Securities Exchange Act of 1934, and are thus allowed to provide simplified executive compensation disclosures in our filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in our SEC filings. We cannot predict whether investors will find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 6. Exhibits

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

The certifications attached as Exhibits 32.1 and 32.2 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

ACHIEVE LIFE SCIENCES, INC.

Date: November 6, 2019

By: /s/ Richard Stewart
Richard Stewart
Chairman and Chief Executive Officer

Date: November 6, 2019

By: /s/ John Bencich
John Bencich
Executive Vice President, Chief Financial Officer and Chief Operating Officer

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, Richard Stewart, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Achieve Life Sciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2019

/s/ Richard Stewart
Richard Stewart
Chairman and Chief Executive Officer

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, John Bencich, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Achieve Life Sciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2019

/s/ John Bencich
John Bencich
Executive Vice President, Chief Financial Officer and Chief Operating Officer

Exhibit 32.1

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Richard Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Quarterly Report on Form 10-Q of the Company for the three and nine months ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

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

Dated: November 6, 2019

/s/ Richard Stewart
Richard Stewart
Chairman and Chief Executive Officer

Exhibit 32.2

Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, John Bencich, Chief Financial Officer of Achieve Life Sciences, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Quarterly Report on Form 10-Q of the Company for the three and nine months ended September 30, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

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

Dated: November 6, 2019

/s/ John Bencich
John Bencich
Executive Vice President, Chief Financial Officer and Chief Operating Officer