

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED September 30, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission file number 033-80623

Achieve Life Sciences, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

95-4343413
(I.R.S. Employer
Identification Number)

1001 W. Broadway, Suite 400, Vancouver, British Columbia, V6H 4B1
(Address of Principal Executive Offices)

(604) 736-3678
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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.

Class	Outstanding at November 7, 2018
Common Stock, \$0.001 par value	6,721,103

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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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents <i>[note 6]</i>	\$ 11,755	\$ 5,284
Restricted cash <i>[note 6 and note 9]</i>	—	222
Short-term investments <i>[note 6]</i>	1,390	—
Amounts receivable	25	9
Prepaid expenses	349	393
Total current assets	<u>13,519</u>	<u>5,908</u>
Restricted cash <i>[note 6]</i>	50	50
Property and equipment, net	32	59
Other assets	141	309
License agreement <i>[note 2, 4 and 5]</i>	2,365	2,532
Goodwill <i>[note 2 and 5]</i>	1,034	1,034
Total assets	<u>\$ 17,141</u>	<u>\$ 9,892</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 458	\$ 213
Accrued liabilities other	755	438
Accrued clinical liabilities	667	877
Accrued compensation	1,071	458
Current portion of long-term obligations <i>[note 9]</i>	11	27
Total current liabilities	<u>2,962</u>	<u>2,013</u>
Long-term obligations, less current portion <i>[note 9]</i>	15	—
Total liabilities	<u>2,977</u>	<u>2,013</u>
Commitments and contingencies <i>[note 9]</i>		
Stockholders' equity:		
Series A convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized, 652 issued and outstanding at September 30, 2018 and zero issued and outstanding at December 31, 2017.	—	—
Common stock, \$0.001 par value, 150,000,000 shares authorized, 4,901,095 and 1,195,675 issued at September 30, 2018 and December 31, 2017, respectively, and 4,901,095 and 1,194,793 outstanding at September 30, 2018 and December 31, 2017, respectively.	16	12
Additional paid-in capital	35,887	20,556
Accumulated deficit	(21,744)	(12,694)
Accumulated other comprehensive income	5	5
Total stockholders' equity	<u>14,164</u>	<u>7,879</u>
Total liabilities and stockholders' equity	<u>\$ 17,141</u>	<u>\$ 9,892</u>
Going concern <i>[note 1]</i>		
Subsequent events <i>[note 11]</i>		

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,	
	2018	2017	2018	2017
EXPENSES				
Research and development	1,541	825	3,787	948
General and administrative	1,753	1,550	5,317	1,902
Total operating expenses	<u>3,294</u>	<u>2,375</u>	<u>9,104</u>	<u>2,850</u>
OTHER INCOME (EXPENSE)				
Interest income	61	9	88	9
Bargain purchase gain [note 2]	—	1,272	—	1,272
Contingent value rights recovery [note 2]	—	200	—	200
Change in value of warrant liability	—	111	—	111
Loss on disposition of intangible asset [note 4]	—	(8,610)	—	(8,610)
Other expenses	(7)	(7)	(34)	(26)
Total other income (expense)	<u>54</u>	<u>(7,025)</u>	<u>54</u>	<u>(7,044)</u>
Net loss before income taxes	\$ (3,240)	\$ (9,400)	\$ (9,050)	\$ (9,894)
Recovery of deferred income taxes [note 4]	—	2,928	—	3,051
Net loss	<u>(3,240)</u>	<u>(6,472)</u>	<u>(9,050)</u>	<u>(6,843)</u>
OTHER COMPREHENSIVE LOSS				
Net unrealized gain (loss) on foreign exchange	—	—	—	—
Total other comprehensive income	—	—	—	—
Comprehensive loss	\$ (3,240)	\$ (6,472)	\$ (9,050)	\$ (6,843)
Basic and diluted net loss per common share	<u>\$ (0.71)</u>	<u>\$ (8.96)</u>	<u>\$ (3.70)</u>	<u>\$ (28.10)</u>
Shares used in computation of basic and diluted net loss per common share	<u>4,533,943</u>	<u>722,583</u>	<u>2,448,962</u>	<u>243,510</u>

See accompanying notes

Achieve Life Sciences, Inc.
Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2018	2017
Operating Activities:		
Net loss	\$ (9,050)	\$ (6,843)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in value of warrant liability <i>[note 6 and note 7 [f]]</i>	—	(111)
Depreciation and amortization <i>[note 4]</i>	220	191
Deferred income tax (recovery) <i>[note 2 and note 4]</i>	—	(3,051)
Stock-based compensation <i>[note 7 [c] and note 7 [d]]</i>	588	152
Bargain purchase gain <i>[note 2]</i>	—	(1,272)
Loss on disposition <i>[note 2]</i>	—	8,610
Contingent value rights liability recovery <i>[note 2]</i>	—	(200)
Changes in operating assets and liabilities:		
Amounts receivable	(16)	(164)
Prepaid expenses and other assets	212	(1,597)
Accounts payable	245	400
Accrued liabilities other	317	(1,123)
Accrued clinical liabilities	(210)	162
Accrued compensation	613	(685)
Lease obligation	(1)	47
Net cash used in operating activities	(7,082)	(5,484)
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	1,274	—
Proceeds from purchase agreement with Lincoln Park Capital, net of issuance costs	1,280	1,129
Taxes paid related to net share settlement of equity awards	—	(22)
Net cash provided by financing activities	14,747	1,107
Investing Activities:		
Purchase of property and equipment	(36)	—
Proceeds on disposal of assets	10	—
Purchase of investments	(1,390)	—
Cash received on reverse merger of OncoGenex <i>[note 2]</i>	—	12,376
Net cash provided by investing activities	(1,416)	12,376
Effect of exchange rate changes on cash	—	7
Net increase (decrease) in cash, cash equivalents and restricted cash	6,249	8,006
Cash, cash equivalents and restricted cash at beginning of the period	5,556	15
Cash, cash equivalents and restricted cash at end of the period	<u>\$ 11,805</u>	<u>\$ 8,021</u>

See accompanying notes.

Achieve Life Sciences, Inc.
Notes to Consolidated Financial Statements
(Unaudited)

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Achieve Life Sciences, Inc. (referred to as “Achieve,” “we,” “us,” or “our”) is a clinical-stage pharmaceutical company, incorporated in the state of Delaware, and operate out of Vancouver, British Columbia and Seattle, Washington. We are committed to the global development and commercialization of cytisinicline for smoking cessation. The United States Adopted Names, or USAN, Council adopted cytisinicline as the nonproprietary, or generic, name for the substance also known as cytosine in the third quarter of 2018. USAN is responsible for selecting simple, informative and unique generic drug names. The USAN Council establishes logical nomenclature classifications based on pharmacological and/or chemical relationships.

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.

On August 1, 2017, OncoGenex Pharmaceuticals, Inc., or OncoGenex, completed a transaction, or the Arrangement, with Achieve Life Science, Inc., or ALS, as contemplated by the Merger Agreement between ALS and OncoGenex dated January 5, 2017, or the Merger Agreement. Under the terms of the Merger Agreement, OncoGenex changed its name to Achieve Life Sciences, Inc., instituted an one-for-eleven reverse stock split, issued shares of its common stock (after accounting for the elimination of resulting fractional shares) in exchange for all of the outstanding preferred shares, common shares and convertible debentures of ALS, and as a result ALS became a wholly-owned subsidiary of OncoGenex, and is listed on the Nasdaq Capital Market under the ticker symbol ACHV. These consolidated financial statements account for the Arrangement between OncoGenex and ALS as a reverse merger, whereby ALS is deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations for the three and nine month periods ended September 30, 2018 include the results of operations of the combined company. The consolidated results of operations for the three and nine month periods ended September 30, 2017 include our consolidated results of operations and the results of OncoGenex following the completion of the Arrangement on August 1, 2017.

The unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States 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, 2017 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, 2017 and filed with the United States Securities and Exchange Commission, or the SEC, on March 1, 2018.

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.

Liquidity and Going Concern Uncertainty

We have historically experienced recurring losses from operations that have generated an accumulated deficit of \$21.7 million through September 30, 2018. During the three and nine months ended September 30, 2018, we incurred a net loss of \$3.2 million and \$9.1 million, respectively. As of September 30, 2018, we had a cash, cash equivalents and short term investments balance of \$13.2 million and a positive working capital balance of \$10.6 million.

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.

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 (Note 2—Reverse Merger), debt and equity financing (Note 7—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. REVERSE MERGER

The consolidated financial statements account for the Arrangement between us and OncoGenex, whereby OncoGenex acquired all of our outstanding common shares, as a reverse merger wherein we are deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations include the results of operations of the combined company for the three and nine months period ended September 30, 2018. The consolidated results of operations for the three and nine month periods ended September 30, 2017 include only our consolidated results of operations and the results of OncoGenex following the completion of the Arrangement on August 1, 2017.

On August 1, 2017, our stockholders approved the Arrangement described above and on the same date, OncoGenex stockholders approved the Arrangement and a one-for-eleven reverse stock split of its common stock. The reverse stock split occurred immediately prior to the closing of the Arrangement. Resulting fractional shares were eliminated.

Under the purchase method of accounting, OncoGenex's outstanding shares of common stock were valued using the closing price on The Nasdaq Capital Market of \$46.20 as at August 1, 2017. There were 273,670 shares of common stock outstanding on August 1, 2017, immediately prior to closing. The fair value of the OncoGenex outstanding stock options was determined using the Black-Scholes pricing model with the following assumptions: stock price of \$46.20, volatility of 97.23% to 106.63%, risk-free interest rate of 1.31% to 1.54%, and expected lives ranging from 1.82 to 3.31 years. The fair value of the OncoGenex outstanding warrants was determined using the Black-Scholes pricing model with the following assumptions: stock price of \$46.20, volatility of 90.33% to 106.08%, risk-free interest rate of 1.32% to 1.53%, and expected lives ranging from 1.91 to 3.24 years.

The final purchase price is summarized as follows (dollars in thousands, except per share amounts):

Shares of the combined company to be owned by OncoGenex equity holders	273,671
Multiplied by the price per share of OncoGenex stock	\$ 46.20
Value of shares of the combined company owned by OncoGenex equity holders	\$ 12,643
Fair value of options and warrants assumed	\$ 207
Fair value of contingent value rights assumed	\$ 200
Total purchase price	<u>\$ 13,050</u>

Under the purchase method of accounting, the total purchase price as shown in the table above is allocated to the OncoGenex net tangible and identifiable intangible assets acquired and liabilities assumed based on their fair values as of the date of the completion of the Arrangement. The final purchase price allocation is as follows (in thousands):

Cash, cash equivalents and marketable securities	12,376
Prepaid expenses and other assets	518
Intangible assets license agreements	8,610
Accounts payable, accrued expenses and other liabilities	(4,054)
Deferred tax liability	(2,928)
Contingent value rights	(200)
Excess negative goodwill	<u>(1,272)</u>
Total purchase price	13,050

In accordance with ASC 805, "Business Combinations," any excess of fair value of acquired net assets over purchase price (negative goodwill) has been recognized as a gain in the period the Arrangement was completed. We have reassessed whether all acquired assets and assumed liabilities have been identified and recognized and performed remeasurements to verify that the consideration paid, assets acquired, and liabilities assumed have been properly valued. The remaining excess has been recognized as a gain. There was no other impact to other comprehensive income.

OncoGenex issued contingent value rights, or each, a CVR and collectively, the CVRs, on July 31, 2017 to their existing stockholders as of July 27, 2017. One CVR was a non-transferable right to potentially receive certain cash, equity or other consideration received by us in the event that we received any such consideration during the five-year period after consummation of the Arrangement as a result of the achievement of certain clinical milestones, regulatory milestones, sales-based milestones and/or up-front payment milestones relating to apatosen, or the Milestones, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between us and an as of yet unidentified third party, as rights agent, or the CVR Agreement. The aggregate consideration to be distributed to the holders of the CVRs would have been equal to 80% of the consideration received by us as a result of the achievement of the Milestones less certain agreed to offsets, as determined pursuant to the CVR Agreement.

The contingent value rights expired on August 17, 2017, as we did not enter into any term sheets or agreement with third parties for the development or commercialization of apatosen. A recovery of \$0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss in 2017.

Pro Forma Results of Operations

The results of operations of OncoGenex are included in our consolidated financial statements from the date of the completion of the transaction on August 1, 2017. The following table presents pro forma results of operations and gives effect to the business combination transaction as if the transaction was consummated at the beginning of the period presented. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the retrospective periods or of the results that may occur in the future.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net loss applicable to common shareholders	\$ (3,240)	\$ (9,730)	\$ (9,050)	\$ (10,100)
Net loss per share-basic and diluted	\$ (0.71)	\$ (13.47)	\$ (3.70)	\$ (41.48)
Weighted average shares	4,533,943	722,583	2,448,962	243,510

3. 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, 2017 in our Annual Report on Form 10-K filed with the SEC, on March 1, 2018. Since December 31, 2017, there have been no material changes to our critical accounting policies or the methodologies or assumptions we apply under them.

Pending Adoption of Recent Accounting Pronouncements

On February 2016, the Financial Accounting Standards Board, or FASB, issued its new leases standard, ASU No. 2016-02, Leases (Topic 842), or ASU 2016-02. ASU 2016-02 is aimed at putting most leases on lessees' balance sheets, but it would also change aspects of lessor accounting. ASU 2016-02 is effective for public business entities for annual periods beginning after December 15, 2019 and interim periods within that year. This standard is expected to have an impact on our accounting for our lease arrangements, particularly our current operating lease arrangements, as well as our disclosures.

Recently Adopted Accounting Policies

In May 2014, the FASB issued 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 15 December 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after 15 December 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.

4. 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 agreements, related to OncoGenex's product candidate apatorsen, upon the acquisition of OncoGenex on August 1, 2017. As at the date of the acquisition, the agreements were determined to have a fair value of \$8.6 million with an estimated useful life of 6 years. (Note 2—Reverse Merger)

In August 2017, we discontinued further development of apatorsen. We provided a notice of discontinuance to our former development partners for apatorsen, Ionis Pharmaceuticals, Inc., or Ionis, and a letter of termination to the University of British Columbia, or UBC, notifying them that we have discontinued development of apatorsen resulting in termination of all licensing agreements related to this product candidate. We believe that all financial obligations, other than continuing mutual indemnification obligations and our requirement to pay for out-of-pocket patent expenses incurred up to the date of termination and for abandoning the apatorsen patents and patent applications, under all apatorsen related agreements with Ionis and UBC, are no longer owed and no further payments are due. We recognized a loss on disposition of apatorsen of \$8.6 million and a deferred income tax recovery of \$2.9 million as a result of discontinuing the development program and providing a notice of discontinuance of the license agreements with Ionis.

We acquired license and supply agreements, in relation to cytosinicine 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, 2018			December 31, 2017		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	\$ 3,117	\$ (752)	\$ 2,365	\$ 3,117	\$ (585)	\$ 2,532

For the three and nine months ended September 30, 2018 we recorded license agreement amortization expense of \$0.1 million and \$0.2 million. For the three and nine months ended September 30, 2017 we recorded license agreement amortization expense of \$0.1 million and \$0.2 million. The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2018:

Year Ending December 31,	
2018	55
2019	223
2020	223
2021	223
2022	223
Thereafter	1,418
Total	\$ 2,365

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 impairment analysis for long lived assets, including the license and supply agreements for the active pharmaceutical ingredient cytisinicline, and concluded no impairment has occurred as of September 30, 2018.

5. 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, Achieve 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 cytosinicline across all therapeutic categories from the University of Bristol from research activities into cytosinicline 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, 2018, we have 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 had provided 100 grams of cytosinicline to the University of Bristol as an initial contribution.

Ionis and UBC License Agreements

In August 2017, we discontinued further development of apatorsen. We provided a notice of discontinuance to our former development partners for apatorsen, Ionis Pharmaceuticals, Inc., or Ionis, and a letter of termination to the University of British Columbia, or UBC, notifying them that we have discontinued development of apatorsen resulting in termination of all licensing agreements related to this product candidate. We believe that all financial obligations, other than continuing mutual indemnification obligations and our requirement to pay for out-of-pocket patent expenses incurred up to the date of termination and for abandoning the apatorsen patents and patent applications, under all apatorsen related agreements with Ionis and UBC, are no longer owed and no further payments are due.

6. 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.

Warrants

As of September 30, 2018, the fair value of the warrant liability was insignificant. We reassess the fair value of the common stock warrants classified as liabilities at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. 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 for a period that coincides with the expected life of the warrants that are classified as liabilities. Warrants that are classified as liabilities are categorized in Level 3 of the fair value hierarchy. A small change in the estimates used may have a relatively large change in the estimated valuation. Warrants that are classified as equity are not considered liabilities and therefore are not reassessed for their fair values at each reporting date.

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, 2018	Level 1	Level 2	Level 3	Total
Assets				
Cash	\$ 2,936	\$ —	\$ —	\$ 2,936
Money market securities (cash equivalents)	8,819	—	—	8,819
Restricted cash (Note 6)	50	—	—	50
Corporate bonds and commercial paper (short term investments)	—	1,390	—	1,390
Total assets	\$ 11,805	\$ 1,390	\$ —	\$ 13,195

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

<u>September 30, 2018</u>	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	\$ 2,936	\$ —	\$ —	\$ 2,936
Money market securities	8,819	—	—	8,819
Total cash and cash equivalents	\$ 11,755	\$ —	\$ —	\$ 11,755
Money market securities (restricted cash)	50	—	—	50
Total restricted cash	\$ 50	\$ —	\$ —	\$ 50
Corporate bonds and commercial paper	\$ 1,390	—	—	\$ 1,390
Total short-term investments	\$ 1,390	\$ —	\$ —	\$ 1,390

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, 2018 and 2017.

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.

7. 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, the Company filed an amendment to its Articles of Incorporation and effected as of May 23, 2018 a one-for-ten reverse stock split of its issued and outstanding shares of common stock, \$0.001 par value and a certificate of amendment to its 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.

From September 14, 2017 through September 30, 2018, we offered and sold 183,378 shares of our common stock pursuant to our Purchase Agreement with LPC, including the 32,895 shares that were part of the initial purchase of Units. These sales resulted in gross proceeds to us of approximately \$3.6 million and offering expenses of \$0.5 million. As of September 30, 2018 shares of our common stock having an aggregate value of approximately \$7.4 million remained available for sale under this offering program. However, pursuant to the terms of the June 2018 underwritten public offering, we are restricted from utilizing the Purchase Agreement, or any variable rate transaction that results in additional shares of our common stock being issued at a price that is based upon or varies with our common stock trading price, for six months following the closing date.

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 the June 19, 2018, (i) the volume weighted average price of our common stock for each of 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 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 Over-allotment 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 Over-allotment 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, 2018, 8,506 shares of the Series A Convertible Preferred Stock had been converted into 2,126,500 shares of common stock, and 652 shares of the Series A Convertible Preferred Stock remained outstanding.

Equity Award Issuances and Settlements

During the three and nine months ended September 30, 2018 and 2017, we issued no shares of common stock to satisfy stock options exercises and 5,340 shares of common stock to satisfy restricted stock unit settlements.

2018 Equity Incentive Plan

As of September 30, 2018, we had reserved, pursuant to the 2018 Equity Incentive Plan, or the 2018 Plan, 1,000,000 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 386,650 were reserved for options currently outstanding and 613,350 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, 2018, 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, 2018, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 21,079 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 15,156 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, 2017	111,578	\$ 80.01
Granted	554,400	2.81
Forfeited	(393)	160.79
Balance, September 30, 2018	665,585	\$ 15.65

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,	
	2018	2017
Risk-free interest rates	2.93 %	1.95 %
Expected dividend yield	0 %	0 %
Expected life	5.68	6.00
Expected volatility	88.23 %	86.06 %

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,	
	2018	2017	2018	2017
Research and development	\$ 70	\$ 43	\$ 190	\$ 43
General and administrative	\$ 140	109	398	109
Total stock-based compensation	\$ 210	\$ 152	\$ 588	\$ 152

As of September 30, 2018 and December 31, 2017, the total unrecognized compensation expense related to stock options granted was \$2.6 million and \$2.0 million, respectively, which is expected to be recognized as expense over a period of approximately 3.1 years from September 30, 2018.

For the three and nine months ended September 30, 2018, a total of 3,854,505 shares, consisting of 3,173,764 warrants, 665,585 options and 15,156 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 2017, a total of 174,408 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, 2018, we recorded a compensation expense of \$37,000 and \$0.1 million, related to these awards, compared to \$0.1 million and \$0.1 million for the three and nine months ended September 30, 2017.

The following table summarizes our restricted stock unit award activity during the nine months ended September 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, December 31, 2017	21,066	\$ 38.87
Released	(5,340)	55.62
Forfeited or expired	(570)	97.03
Balance, September 30, 2018	15,156	\$ 30.78

As of September 30, 2018, we had approximately \$0.4 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 2.8 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

The following is a summary of outstanding warrants to purchase common stock at September 30, 2018:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	25,272	440.00	July 2019
(2) Series B Warrants issued in July 2014 financing	6,093	440.00	July 2019
(3) Series A-1 Warrants issued in April 2015 financing	2,175	264.00	October 2020
(4) Warrants issued in September 2017 financing	8,224	34.96	March 2023
(5) Warrants issued in June 2018 financing	3,132,000	4.00	June 2023

For the three and nine months ended September 30, 2018, 187,500 and 318,000, respectively, of the warrants issued in the June 2018 financing were exercised at a per unit price of \$4.00, for proceeds of \$0.8 million and \$1.3 million, respectively. No warrants were exercised during the three and nine months ended September 30, 2017. The Series A-1 Warrants assumed by us as part of the Arrangement, the warrants issued in the September 2017 financing and the warrants issued in the June 2018 financing, are classified as equity. The Series A and Series B warrants assumed by us as part of the Arrangement are classified as liabilities. The estimated fair value of warrants classified as liabilities is reassessed at each reporting date using the Black-Scholes pricing model. As at September 30, 2018 and Dec 31, 2017, the fair value of the warrants was insignificant.

8. RELATED PARTY TRANSACTIONS

We entered into a consulting agreement with Ricanto, Ltd., or Ricanto, on September 17, 2015 to provide strategic consulting and advice concerning clinical development, regulatory matters and business planning. Richard Stewart and Anthony Clarke together own 100% of Ricanto. Richard Stewart is our Chief Executive Officer, or CEO, Chairman of the Board, and a principal stockholder. Anthony Clarke is our Chief Scientific Officer, President, a board director, and a principal stockholder. We incurred consulting fees from Ricanto of \$0.1 million during the nine months ended September 30, 2016. The consulting agreement with Ricanto was

terminated on August 1, 2017, immediately prior to the closing of the Arrangement. We did not incur any consulting fees from Ricanto in 2017. As of December 31, 2016, we recorded amounts payable to Ricanto of \$0.6 million in accrued liabilities on our balance sheet. On July 18, 2017, Ricanto converted all amounts owed to it, totaling \$0.6 million, into 475 shares of our common stock, prior to the closing of the Arrangement, par value \$0.01. Pursuant to the terms of the Arrangement, each share was converted into, approximately 17,067 shares of common stock post-conversion. As of September 30, 2018 we had no outstanding amounts payable to Ricanto.

During 2016 we borrowed \$0.2 million in total principal amount through two notes payable dated April 20, 2016 and December 8, 2016 from Richard Stewart. The notes mature and are payable upon demand one year from the date of issuance. Interest accrues at an annual rate of 3.5%. As of December 31, 2016 the outstanding principal, included in shareholder loans with related parties, was \$0.2 million and accrued interest payable was \$3,000. On July 24, 2017, Richard Stewart converted the \$0.2 million, representing the entire amounts of principal and accrued interest owed, into 146 shares of our common stock, prior to the closing of the Arrangement, par value \$0.01. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 5,246 shares of common stock post-conversion. As of September 30, 2018 we had no outstanding principal or accrued interest with the related party.

We borrowed \$2.7 million on May 18, 2015, through a convertible promissory note payable to a Lender of ours. The note matures and is payable upon demand one year from the date of the note. Interest accrues at an annual rate of 3.5%. On September 30, 2015 the Lender converted \$2.0 million in principal into 4,500 shares of our common stock, prior to the closing of the Arrangement, par value \$0.01, and became a principal stockholder. On March 7, 2017 we borrowed \$20,000 through a note payable to the Lender. The note matures and is payable upon demand one year from the date of issuance. Interest accrues at an annual rate of 3.5%. As of December 31, 2016, the outstanding principal balance, included in shareholder loans with related parties, was \$0.7 million and had accrued interest payable of \$35,000. On July 24, 2017, the Lender converted the remaining amounts in principal and accrued interest, totaling \$0.8 million, into 586 shares of our common stock, prior to the closing of the Arrangement, par value \$0.01. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 182,743 shares of common stock post-conversion. As of September 30, 2018 we had no outstanding principal or accrued interest with the related party.

We entered into an employment agreement on May 11, 2015 with one of our principal stockholders to serve as our CEO. We terminated the employment agreement on December 31, 2016. From May 11, 2015 to December 31, 2016, we had not paid any salary specified in the employment agreement. Salary otherwise payable as at December 31, 2016 was \$0.7 million and was accrued on our balance sheet as Accrued compensation. On July 19, 2017 we entered into a separation agreement with our former CEO. Pursuant to the separation agreement, for settlement of all salaries owed, we paid 238 shares of our common stock, prior to the closing of the Arrangement, representing 50% of the total amounts owed as accrued compensation and paid \$0.4 million for the remaining 50%, subsequent to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 8,551 shares of common stock post-conversion. As of September 30, 2018 we had no outstanding principal or accrued interest with the related party.

We entered into an employment agreement on August 17, 2015 with one of our principal stockholders to serve as our Chief Financial Officer, or CFO. We terminated the employment agreement on December 31, 2016. From August 17, 2015 to December 31, 2016, we had not paid any salary specified in the employment agreement. Salary otherwise payable as at December 31, 2016 was \$0.3 million and was accrued on our balance sheet as Accrued compensation. On July 20, 2017 we entered into a separation agreement with our former CFO. Pursuant to the separation agreement, for settlement of all salaries owed and as a separation payment, we paid 127 shares of our common stock, prior to the closing of the Arrangement, representing 50% of the total amounts owed as accrued compensation and paid \$0.2 million for the remaining 50%, subsequent to the closing of the Arrangement. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 4,563 shares of common stock post-conversion. As of September 30, 2018 we had no outstanding principal or accrued interest with the related party.

Michelle Griffin, the spouse of Scott Cormack, OncoGenex's former CEO and a current member of our board of directors, entered into a consulting agreement in 2013 with OncoGenex, which was amended thereafter. Immediately prior to the closing of the Arrangement, the consulting agreement was terminated. Pursuant to the consulting agreement, OncoGenex was obligated to pay to the consultant a termination fee of \$0.6 million, which was accrued in OncoGenex's accrued liabilities immediately prior to the closing of the Arrangement. Subsequent to the closing of the Arrangement, we paid the full amount of the termination fees and no amounts were accrued on our balance sheet as at September 30, 2018.

9. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of September 30, 2018 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Vancouver office operating lease	\$ 32	\$ 32	\$ —	\$ —	\$ —
Seattle office operating lease	\$ 352	\$ 143	\$ 209	\$ —	\$ —
Total	\$ 384	\$ 175	\$ 209	\$ —	\$ —

Lease Arrangements

We have an operating lease agreement for office space being used in Vancouver, Canada, which expires in January 2019. Pursuant to the operating lease agreement, we have the option to terminate the lease early without penalty at any time after January 1, 2018 so long as we provide three months prior written notice to the landlord.

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

2018	24
2019	8
Total	\$ 32

In July 2018, we entered into an amendment of our operating lease agreement for office space in Vancouver, Canada, on the same financial terms, to extend the lease through the end of January 2019.

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

2018	35
2019	144
2020	148
2021	25
Total	\$ 352

Consolidated rent and operating expense relating to the Vancouver, Canada, Bothell, Washington and Seattle, Washington offices for the three and nine months ended September 30, 2018 was \$0.1 million and \$0.2 million, respectively. Consolidated rent expense for the three and nine months ended September 30, 2017 was \$0.1 million and \$0.1 million, respectively.

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, 2018.

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.

10. SEVERANCE CHARGES

As a requirement for the closing of the Arrangement, OncoGenex terminated the employment of one senior executive. Severance payable at the date of the transaction was \$1.2 million and has been accounted for in accordance with EITF No. 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination" as part of the purchase price allocation (Note 4—Intangibles). The severance payable was settled following the completion of the Arrangement and no amounts were owing as at September 30, 2018.

11. SUBSEQUENT EVENTS

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.

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:

- progress and preliminary and future results of any clinical trials;
- our anticipated future capital requirements and the terms of any capital financing agreements;
- 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. The United States Adopted Names, or USAN, Council adopted cytisinicline as the nonproprietary, or generic, name for the substance also known as cytisine in the third quarter of 2018. USAN is responsible for selecting simple, informative and unique generic drug names. The USAN Council establishes logical nomenclature classifications based on pharmacological and/or chemical relationships. Our focus is to address the global smoking health epidemic, which is a leading cause of preventable death and is responsible for approximately seven million deaths annually worldwide.

Cytisinicline is an established 25-day 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 by interacting with nicotine receptors 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 smoking through antagonistic properties. The cytisinicline dosing schedule reflects that of an anti-addiction medication, with downward dose titration over a period of 25 days.

Investigational New Drug, or IND-enabling, non-clinical toxicology studies completed to date have been sponsored by the National Center for Complementary and Integrative Health, or NCCIH, division of the National Institutes of Health, or NIH, in addition to the

National Cancer Institute. In June 2017, we filed our IND application for cytisinicline with the U.S Food and Drug Administration, or FDA, which included NCCIH sponsored non-clinical studies.

In August 2017, we initiated a 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 study assessing the repeat-dose Pharmacokinetics, or PK, and Pharmacodynamics, or PD, effects of 1.5mg and 3mg cytisinicline in 36 healthy volunteer smokers when administered over the standard 25-day course of treatment. Of the 36 subjects, 24 were to be 18-65 years and 12 were to be greater than 65 years of age. Preliminary results on the 24 smokers (18-65 years) were announced in February 2018. The PK results indicated expected increases in plasma concentration with higher doses of cytisinicline. Smokers in the study were not required to have a designated or predetermined quit date, however, 58% of the subjects in the trial achieved biochemically verified smoking abstinence by day 26. Subjects who did not achieve abstinence had a significant reduction in number of daily cigarettes smoked by day 26. The adverse events observed were mostly mild with transient headaches as the most commonly reported event. No serious adverse events were observed in the study. The study was concluded with a total of 26 subjects in October 2018 with only 2 of the intended 12 subjects enrolled in the greater than age 65 cohort. We expect final study results to be available in the first quarter of 2019.

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 submitted to the IND in the first quarter of 2018 and 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 the co-administered drug.

We have met with the FDA and with other national regulatory authorities in Europe to identify the steps required for the approval of cytisinicline. Our most recent meeting was an end of Phase 2 meeting with the FDA in May of 2018 to review and receive guidance on our Phase 3 clinical program and overall development plans for cytisinicline to support a New Drug Application, or NDA. This recent 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 human 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.

A new cytisinicline tablet with improved shelf life has been formulated and recently launched commercially by Sopharma 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 concluded bioequivalence when cytisinicline was administered with or without food. 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 mg dose of this new formulation of cytisinicline was well tolerated.

In October 2018, we initiated the ORCA-1 trial, a Phase 2b optimization study in approximately 250 smokers in the U.S. ORCA-1 is the first in Achieve's ORCA (Ongoing Research of Cytisinicline for Addiction) Program that aims to evaluate the effectiveness of cytisinicline for smoking cessation and potentially other indications. This Phase 2b trial will evaluate both the 1.5mg and 3mg doses of cytisinicline on a declining titration schedule over 25 days, as well as three times daily dosing. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. The primary efficacy endpoint is reduction in the number of cigarettes consumed during treatment with secondary analyses to be conducted on smoking cessation rates, safety, and compliance. ORCA-1 is being conducted at eight centers across the U.S. and results are expected in mid-2019.

We previously were developing apatorsen, of which we discontinued further development in August 2017. We provided a notice of discontinuance to our former development partners for apatorsen, Ionis Pharmaceuticals, Inc., or Ionis, and a letter of termination to the University of British Columbia, or UBC, notifying them that we have discontinued development of apatorsen resulting in termination of all licensing agreements related to this product candidate. We believe that all financial obligations, other than continuing mutual indemnification obligations and our requirement to pay for out-of-pocket patent expenses incurred up to the date of termination and for abandoning the apatorsen patents and patent applications, under all apatorsen related agreements with Ionis and UBC, are no longer owed and no further payments are due.

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 \$3.2 million and \$9.1 million for the three and nine months ended September 30, 2018, respectively. Our net loss was \$6.5 million and \$6.8 million for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$21.7 million, cash, cash equivalents and short term investments balance of \$13.2 million and a positive working capital balance of \$10.6 million.

Substantially all of our operating losses resulted from expenses incurred from general and administrative costs associated with our operations and research and development costs from our clinical development programs.

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.

Recent Corporate History

On August 1, 2017, OncoGenex Pharmaceuticals, Inc., or OncoGenex, completed a transaction, or the Arrangement, with Achieve Life Science, Inc., or ALS, as contemplated by the Merger Agreement between ALS and OncoGenex dated January 5, 2017, or the Merger Agreement. Under the terms of the Merger Agreement, OncoGenex changed its name to Achieve Life Sciences, Inc., instituted an one-for-eleven reverse stock split, issued shares of its common stock (after accounting for the elimination of resulting fractional shares) in exchange for all of the outstanding preferred shares, common shares and convertible debentures of ALS, and as a result ALS became a wholly-owned subsidiary of OncoGenex, and is listed on the Nasdaq Capital Market under the ticker symbol ACHV. More information concerning the Arrangement is contained in our Current Report on Form 8-K filed on August 2, 2017 and our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC on June 6, 2017.

The consolidated financial statements account for the Arrangement between us and OncoGenex, whereby OncoGenex acquired all of our outstanding common shares, as a reverse merger wherein we are deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations include the results of operations of the combined company for the three and nine month period ended September 30, 2018. The consolidated results of operations for the three and nine month periods ended September 30, 2017 includes our consolidated results of operations and the results of OncoGenex following the completion of the Arrangement on August 1, 2017. This treatment and presentation is in accordance with ASC 805, "Business Combinations".

In connection with the Arrangement, OncoGenex issued contingent value rights, or CVRs, on July 31, 2017 to their existing stockholders as of July 27, 2017. One CVR was issued for each share of their common stock outstanding as of the record date for such issuance. The CVRs expired on August 17, 2017. A recovery of \$0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss in 2017.

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, 2018, we have 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, human resources and intellectual property. Other costs include professional fees for legal and auditing services, insurance and facility costs.

Warrant Liability

The following is a summary of outstanding warrants to purchase common stock that are classified as liabilities at September 30, 2018:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	25,272	440.000	July 2019
(2) Series B Warrants issued in July 2014 financing	6,093	440.000	July 2019

No warrants classified as liabilities were exercised during the three and nine months ended September 30, 2018 or 2017.

We reassess the fair value of the common stock warrants classified as liabilities at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. 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.

Results of Operations

For the three and nine months ended September 30, 2018 and 2017

Research and development expenses

Our research and development expenses for our clinical development program for the three and nine months ended September 30, 2018 and 2017 are as follows (in thousands):

	Three months ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Clinical development programs:				
Cytisinicline	\$ 1,541	\$ 825	\$ 3,787	\$ 948
Total research and development expenses	\$ 1,541	\$ 825	\$ 3,787	\$ 948

Research and development expenses for the three and nine months ended September 30, 2018 increased to \$1.5 million and \$3.8 million from \$0.8 million and \$0.9 million for the three and nine months ended September 30, 2017, respectively. The increase in 2018 as compared to 2017 was due to increased research and development activity for our cytinicline clinical development program, including costs associated with the repeat dose pharmacokinetics trial, and a food effect study on a new cytinicline formulation and increased employee expenses and facilities costs resulting from the Arrangement.

General and administrative expenses

General and administrative expenses for the three and nine months ended September 30, 2018 increased to \$1.8 million and \$5.3 million from \$1.6 million and \$1.9 million for the three and nine months ended September 30, 2017. The increase in 2018 as compared to 2017 was due to increases in employee headcount, consulting fees, legal fees and professional fees as a result of the closing of the Arrangement and the integration of OncoGenex with our operations.

Liquidity and Capital Resources

We have incurred an accumulated deficit of \$21.7 million through September 30, 2018 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, 2018, we had a cash, cash equivalents and short term investments balance of \$13.2 million and a positive working capital balance of \$10.6 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 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, 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.

From September 14, 2017 through November 7, 2018, we offered and sold 183,378 shares of our common stock pursuant to our Purchase Agreement with LPC, including the 32,895 shares that were part of the initial purchase of Units. These sales resulted in gross proceeds to us of approximately \$3.6 million and offering expenses of \$0.5 million. As of November 7, 2018, shares of our common stock having an aggregate value of approximately \$7.4 million remained available for sale under this offering program. However,

pursuant to the terms of the June 2018 underwritten public offering, we are restricted from utilizing the Purchase Agreement, or any variable rate transaction that results in additional shares of our common stock being issued at a price that is based upon or varies with our common stock trading price, for six months following the closing date.

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 the June 19, 2018, (i) the volume weighted average price of our common stock for each of 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 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.

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

From June 19, 2018 to November 7, 2018, 8,579 shares of the Series A Convertible Preferred Stock had been converted into 2,144,750 shares of common stock, and 579 shares of the Series A Convertible Preferred Stock remained outstanding.

From June 19, 2018 through November 7, 2018, 330,500 of the warrants issued in the June 2018 financing were exercised at a per unit price of \$4.00, for proceeds of approximately \$1.3 million and 3,119,500 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.

Cash Flows

Cash Used by Operations

For the nine months ended September 30, 2018, net cash used in operating activities was \$7.1 million compared to \$5.5 million for the nine months ended September 30, 2017. The increase in cash used in operations in 2018 as compared to 2017 was primarily attributable to increased personnel and facilities assumed in the Arrangement and increased research and development expenses for our cytisinicline program.

Cash Provided by Financing Activities

For the nine months ended September 30, 2018, net cash provided by financing activities was \$14.7 million compared to \$1.1 million for the nine months ended September 30, 2017. Net cash provided by financing activities in the nine months ended September 30, 2018 relates to proceeds received from our June 2018 financing, our September 2018 financing, our purchase agreement with LPC and exercise of warrants. Net cash provided by financing activities in the nine months ended September 30, 2017 relates to proceeds from promissory notes payable to a certain shareholder.

Cash Used by Investing Activities

Net cash used by investing activities for the nine months ended September 30, 2018 was \$1.4 million compared to \$12.4 million provided by for the nine months ended September 30, 2017. Net cash used by investing activities in the nine months ended September 30, 2018 relates to transactions involving marketable securities in the normal course of business and the purchase of capital assets. Net cash provided by investing activities in the nine months ended September 30, 2017 relates to the reverse merger with OncoGenex.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet financing arrangements at September 30, 2018.

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, 2017, as filed with the SEC on March 1, 2018. 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 2017 Form 10-K. For more information regarding our current contingencies and commitments, see note 9 to the financial statements included above.

Material Changes in Financial Condition

(in thousands)	September 30,	December 31,
	2018	2017
Total Assets	\$ 17,141	\$ 9,892
Total Liabilities	2,977	2,013
Total Equity	14,164	7,879

The increase in assets at September 30, 2018 compared to December 31, 2017 was due to proceeds received from our June 2018 financing, September 2018 financing, our purchase agreement with Lincoln Park and the exercise of our warrants. The increase in liabilities at September 30, 2018 compared to December 31, 2017 was primarily due to higher clinical related trade payables associated with increased cytisinicline development activity.

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, 2017 in our Annual Report on Form 10-K filed with the SEC, on March 1, 2018. Since December 31, 2017, 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 2018 and the future adoption of recently issued accounting standards. We expect the adoption of ASU No. 2016-02, Leases, to have 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, 2018, 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, 2018 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, Integration and Capital Requirements

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 pre-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;
- continue efforts to discover new product candidates;
- seek to 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.

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 activities and clinical trials and regulatory approvals.

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 capital 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 pre-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 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 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, 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 and commercialization, if any, 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 recently completed the merger with OncoGenex Pharmaceuticals, Inc. and the failure to integrate successfully the operations of the combined company could adversely affect our future results.

Our success will depend, in significant part, on our ability to realize the anticipated benefits from combining the operations of the combined Achieve-OncoGenex enterprise. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in our failure to achieve some or all of the anticipated benefits of the merger. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown or currently unquantifiable liabilities associated with the merger and our operations;
- operating as a public company under our combined management team, some members of which have limited public company experience; and
- performance shortfalls as a result of the diversion of the management’s attention caused by integrating the companies’ operations.

We will 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. For example, our management team consists of certain executive officers of Achieve prior to the merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. In addition, it may be more 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 in our post-merger company 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 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 newly 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 newly 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 pre-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 pre-clinical testing. This 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 pre-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 other ongoing or planned indications for cytisinicline; and
- delays in the time for manufacture 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 pre-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. However, 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. 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 cytosinicline in clinical trials and the sale of cytosinicline 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 cytosinicline may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. During the course of treatment, patients may suffer adverse events for reasons that may be related to cytosinicline. 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 cytosinicline, if any, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to cytosinicline, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals cytosinicline receives or maintains. As a result of these factors, 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 cytosinicline, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to 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 also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that cytosinicline 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;
- the inability to commercialize, or if commercialized, decreased demand for, cytosinicline;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenues;
- 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;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the 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 cytosinicline from the *Laburnum anagyroides* plant, which plant grows in a limited number of locations outside of the United States.

The therapeutic component of our product candidate, cytosinicline, is derived from the seeds of the *Laburnum anagyroides* plant, which grows in the mountains of Southern Europe. We currently secure cytosinicline 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 cytosinicline. Sopharma currently has planted approximately 225 acres of *Laburnum* trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria and is in the process of planting another 150 acres. Sopharma plans to plant additional trees to manage supply for major markets. Each tree takes approximately four to five 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 that the trees will produce the anticipated yield of cytosinicline. 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 other weather conditions. As a result of such events, we could experience cytisinicline shortages from Sopharma, all of 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. The failure of us to meet such regulatory requirements 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 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.

Risks Related to Regulatory Approval of Cytisinicline and Other Legal Compliance Matters

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 cytisnicline 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;
- 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 Health Care and Education Reconciliation Act, or the Health Care 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 health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and 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 Health Care Reform Law was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Health Care 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 Health Care Reform Law and we expect that additional state and federal healthcare measures under the Trump administration will 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 Health Care Reform Law provides coverage for smoking cessation-related activities, including two counseling attempts for smoking cessation per year and prescription drugs for smoking cessation, but not over-the-counter treatments. 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.

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 Welch. In addition, although we have entered into employment agreements with each of Mr. Stewart, Mr. Bencich, Dr. Jacobs, Dr. Clarke and Ms. Welch, 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 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. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If 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.

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 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.

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 Polanica, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, zpharm, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm, Adamed, Aflofarm 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 pre-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-party payors, 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 health care 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 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; and
- 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 health care 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 a 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 to develop 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 pre-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 and intend to file patent applications in the United States 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 cytinicline and there is no guarantee that such patents will be issued or if issued, will be broad enough to prevent competitors from developing competing cytinicline 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 that of 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 cytinicline 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 cytinicline 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 health care payment systems; and
- period-to-period fluctuations in our financial results.

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 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 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 to LPC 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 8,000 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 \$20.00 per share. The sale of additional shares of our common stock pursuant to our purchase agreement with LPC has or will have a dilutive impact on our existing stockholders. Sales by us to LPC could cause the market price of our common stock to decline significantly. Sales of our common stock under the purchase 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 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 may seek to raise additional financing 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
3.1	<u>Amendment to Sixth Amended and Restated Bylaws.</u>
4.1	<u>Form of Common Stock Purchase Warrant (2018 Private Placement) (Incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on October 1, 2018.)</u>
10.1	<u>Achieve Life Sciences 2018 Equity Incentive Plan</u>
31.1	<u>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</u>
31.2	<u>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</u>
32.1#	<u>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</u>
32.2#	<u>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</u>
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 7, 2018

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

Date: November 7, 2018

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

**AMENDMENT
TO SIXTH AMENDED AND RESTATED BYLAWS OF
ACHIEVE LIFE SCIENCES**

Section 2.3 of the Sixth Amended & Restated Bylaws of Achieve Life Sciences, as adopted on January 5, 2017, shall be amended and replaced in its entirety by the following provision:

2.3. Place of Meeting. All meetings of the stockholders for the election of directors or for any other purpose shall be held either at a place, within or without the State of Delaware, or solely by means of remote communication in accordance with Section 211(a)(2) of the General Corporate Law of the State of Delaware, which may include a virtual meeting, as the board of directors in its sole discretion may determine. If authorized by the board of directors in its sole discretion, and subject to such guidelines and procedures as the board of directors may adopt, any stockholders and proxy holders not physically present at a meeting of stockholders may, by means of remote communication, including virtual meeting technology, (a) participate in a meeting of stockholders and (b) be deemed present in person and vote at a meeting of stockholders; whether such meeting is to be held at a designated place or solely by means of remote communication, provided that (i) the corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxy holder; (ii) the corporation shall implement reasonable measures to provide such stockholders and proxy holders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings; and (iii) if any stockholder or proxy holder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the corporation. Any adjourned session of any meeting of the stockholders shall be held at the place announced at the meeting at which the adjournment is taken.

ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN

1. PURPOSE. The purpose of this Plan is to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to the success of the Company, and any Parents, Subsidiaries and Affiliates that exist now or in the future, by offering them an opportunity to participate in the Company's future performance through the grant of Awards. Capitalized terms not defined elsewhere in the text are defined in Section 28.

2. SHARES SUBJECT TO THE PLAN.

2.1 Number of Shares Available. Subject to Sections 2.6 and 21 and any other applicable provisions hereof, the total number of Shares reserved and available for grant and issuance pursuant to this Plan as of the date of adoption of the Plan by the Board, is 1,000,000, plus (a) any reserved shares not issued or subject to outstanding grants under the Company's 2017 Equity Incentive Plan (the "**Prior Plan**") on the Effective Date, (b) shares that are subject to stock options or other awards granted under the Prior Plan that cease to be subject to such stock options or other awards, by forfeiture or otherwise, after the Effective Date, (c) shares issued under the Prior Plan before or after the Effective Date pursuant to the exercise of stock options that are forfeited after the Effective Date, (d) shares issued under the Prior Plan that are repurchased by the Company at the original issue price and (e) shares that are subject to stock options or other awards under the Prior Plan that are used to pay the exercise price of an option or withheld to satisfy the tax withholding obligations related to any award.

2.2 Lapsed, Returned Awards. Shares subject to Awards, and Shares issued under the Plan under any Award, will again be available for grant and issuance in connection with subsequent Awards under this Plan to the extent such Shares: (a) are subject to issuance upon exercise of an Option or SAR granted under this Plan but which cease to be subject to the Option or SAR for any reason other than exercise of the Option or SAR; (b) are subject to Awards granted under this Plan that are forfeited or are repurchased by the Company at the original issue price; (c) are subject to Awards granted under this Plan that otherwise terminate without such Shares being issued; or (d) are surrendered pursuant to an Exchange Program. To the extent an Award under the Plan is paid out in cash or other property rather than Shares, such cash payment will not result in reducing the number of Shares available for issuance under the Plan. Shares used to pay the exercise price of an Award or withheld to satisfy the tax withholding obligations related to an Award will become available for future grant or sale under the Plan. For the avoidance of doubt, Shares that otherwise become available for grant and issuance because of the provisions of this Section 2.2 shall not include Shares subject to Awards that initially became available because of the substitution clause in Section 21.2 hereof.

2.3 Minimum Share Reserve. At all times the Company shall reserve and keep available a sufficient number of Shares as shall be required to satisfy the requirements of all outstanding Awards granted under this Plan.

2.4 Automatic Share Reserve Increase. The number of Shares available for grant and issuance under the Plan shall be increased on January 1, of each of 2018 through 2027, by the lesser of (a) five percent (5%) of the number of Shares issued and outstanding on each December 31 immediately prior to the date of increase or (b) such number of Shares determined by the Board.

2.5 Limitations. No more than 2,000,000 Shares shall be issued pursuant to the exercise of ISOs.

2.6 Adjustment of Shares. If the number of outstanding Shares is changed by a stock dividend, extraordinary dividends or distributions (whether in cash, shares or other property, other than a regular cash dividend), spin-off, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in the capital structure of the Company, without consideration, then (a) the number of Shares reserved for issuance and future grant under the Plan set forth in Section 2.1, including Shares reserved under sub-clauses (a)–(e) of Section 2.1, (b) the Exercise Prices of and number of Shares subject to outstanding Options and SARs, (c) the number of Shares subject to other outstanding Awards, and (d) the maximum number of Shares that may be issued

as ISOs set forth in Section 2.5 shall be proportionately adjusted, subject to any required action by the Board or the stockholders of the Company and in compliance with applicable securities laws; provided that fractions of a Share will not be issued.

If, by reason of an adjustment pursuant to this Section 2.6, a Participant's Award Agreement or other agreement related to any Award or the Shares subject to such Award covers additional or different shares of stock or securities, then such additional or different shares, and the Award Agreement or such other agreement in respect thereof, shall be subject to all of the terms, conditions and restrictions which were applicable to the Award or the Shares subject to such Award prior to such adjustment.

3. ELIGIBILITY. ISOs may be granted only to Employees. All other Awards may be granted to Employees, Consultants, Directors and Non-Employee Directors; provided such Consultants, Directors and Non-Employee Directors render bona fide services not in connection with the offer and sale of securities in a capital-raising transaction.

4. ADMINISTRATION.

4.1 Committee Composition; Authority. This Plan will be administered by the Committee or by the Board acting as the Committee. Subject to the general purposes, terms and conditions of this Plan, and to the direction of the Board, the Committee will have full power to implement and carry out this Plan, except, however, the Board shall establish the terms for the grant of an Award to Non-Employee Directors. The Committee will have the authority to:

(a) construe and interpret this Plan, any Award Agreement and any other agreement or document executed pursuant to this Plan;

(b) prescribe, amend and rescind rules and regulations relating to this Plan or any Award;

(c) select persons to receive Awards;

(d) determine the form and terms and conditions, not inconsistent with the terms of the Plan, of any Award granted hereunder. Such terms and conditions include, but are not limited to, the exercise price, the time or times when Awards may vest and be exercised (which may be based on performance criteria) or settled, any vesting acceleration or waiver of forfeiture restrictions, the method to satisfy tax withholding obligations or any other tax liability legally due and any restriction or limitation regarding any Award or the Shares relating thereto, based in each case on such factors as the Committee will determine;

(e) determine the number of Shares or other consideration subject to Awards;

(f) determine the Fair Market Value in good faith and interpret the applicable provisions of this Plan and the definition of Fair Market Value in connection with circumstances that impact the Fair Market Value, if necessary;

(g) determine whether Awards will be granted singly, in combination with, in tandem with, in replacement of, or as alternatives to, other Awards under this Plan or any other incentive or compensation plan of the Company or any Parent, Subsidiary or Affiliate;

(h) grant waivers of Plan or Award conditions;

(i) determine the vesting, exercisability and payment of Awards;

(j) correct any defect, supply any omission or reconcile any inconsistency in this Plan, any Award or any Award Agreement;

(k) determine whether an Award has been earned or has vested;

(l) determine the terms and conditions of any, and to institute any Exchange Program;

(m) reduce or waive any criteria with respect to Performance Factors;

(n) adjust Performance Factors to take into account changes in law and accounting or tax rules as the Committee deems necessary or appropriate to reflect the impact of extraordinary or unusual items, events or circumstances to avoid windfalls or hardships;

(o) adopt rules and/or procedures (including the adoption of any subplan under this Plan) relating to the operation and administration of the Plan to accommodate requirements of local law and procedures outside of the United States or qualify Awards for special tax treatment under laws of jurisdictions other than the United States;

(p) make all other determinations necessary or advisable for the administration of this Plan;

(q) delegate any of the foregoing to one or more executive officers pursuant to a specific delegation as permitted by applicable law, including Section 157(c) of the Delaware General Corporation Law; and

(r) to exercise negative discretion on Performance Awards, reducing or eliminating the amount to be paid to Participants.

4.2 Committee Interpretation and Discretion. Any determination made by the Committee with respect to any Award shall be made in its sole discretion at the time of grant of the Award or, unless in contravention of any express term of the Plan or Award, at any later time, and such determination shall be final and binding on the Company and all persons having an interest in any Award under the Plan. Any dispute regarding the interpretation of the Plan or any Award Agreement shall be submitted by the Participant or Company to the Committee for review. The resolution of such a dispute by the Committee shall be final and binding on the Company and the Participant. The Committee may delegate to one or more executive officers the authority to review and resolve disputes with respect to Awards held by Participants who are not Insiders, and such resolution shall be final and binding on the Company and the Participant.

4.3 Section 16 of the Exchange Act. Awards granted to Participants who are subject to Section 16 of the Exchange Act must be approved by two or more “non-employee directors” (as defined in the regulations promulgated under Section 16 of the Exchange Act).

4.4 Documentation. The Award Agreement for a given Award, the Plan and any other documents may be delivered to, and accepted by, a Participant or any other person in any manner (including electronic distribution or posting) that meets applicable legal requirements.

4.5 Foreign Award Recipients. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws and practices in other countries in which the Company and its Subsidiaries and Affiliates operate or have employees or other individuals eligible for Awards, the Committee, in its sole discretion, shall have the power and authority to: (a) determine which Subsidiaries and Affiliates shall be covered by the Plan; (b) determine which individuals outside the United States are eligible to participate in the Plan, which may include individuals who provide services to the Company, Subsidiary or Affiliate under an agreement with a foreign nation or agency; (c) modify the terms and conditions of any Award granted to individuals outside the United States or foreign nationals to comply with applicable foreign laws, policies, customs and practices; (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent the Committee determines such actions to be necessary or advisable (and such subplans and/or modifications shall be attached to this Plan as appendices); provided, however, that no such subplans and/or modifications shall increase the share limitations contained in Section 2.1 hereof; and (e) take any action, before or after an Award is made, that the Committee determines to be necessary or advisable to obtain approval or comply with any local governmental regulatory exemptions or approvals. Notwithstanding the foregoing, the Committee may not take any actions hereunder, and no Awards shall be granted, that would violate the Exchange Act or any other applicable United States securities law, the Code, or any other applicable United States governing statute or law.

5. OPTIONS. An Option is the right but not the obligation to purchase a Share, subject to certain conditions, if applicable. The Committee may grant Options to eligible Employees, Consultants and Directors and will determine whether such Options will be Incentive Stock Options within the meaning of the Code (*“ISOs”*) or Nonqualified Stock Options (*“NSOs”*), the number of Shares subject to the Option, the Exercise Price of the Option, the period during which the Option may vest and be exercised, and all other terms and conditions of the Option, subject to the following terms of this section.

5.1 Option Grant. Each Option granted under this Plan will identify the Option as an ISO or an NSO. An Option may be, but need not be, awarded upon satisfaction of such Performance Factors during any Performance Period as are set out in advance in the Participant’s individual Award Agreement. If the Option is being earned upon the satisfaction of Performance Factors, then the Committee will: (a) determine the nature, length and starting date of any Performance Period for each Option; and (b) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to Options that are subject to different performance goals and other criteria.

5.2 Date of Grant. The date of grant of an Option will be the date on which the Committee makes the determination to grant such Option, or a specified future date. The Award Agreement and a copy of this Plan will be delivered to the Participant within a reasonable time after the granting of the Option.

5.3 Exercise Period. Options may be vested and exercisable within the times or upon the conditions as set forth in the Award Agreement governing such Option; provided, however, that no Option will be exercisable after the expiration of ten (10) years from the date the Option is granted; and provided further that no ISO granted to a person who, at the time the ISO is granted, directly or by attribution owns more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or of any Parent or Subsidiary (*“Ten Percent Stockholder”*) will be exercisable after the expiration of five (5) years from the date the ISO is granted. The Committee also may provide for Options to become exercisable at one time or from time to time, periodically or otherwise, in such number of Shares or percentage of Shares as the Committee determines.

5.4 Exercise Price. The Exercise Price of an Option will be determined by the Committee when the Option is granted; provided that: (a) the Exercise Price of an Option will be not less than one hundred percent (100%) of the Fair Market Value of the Shares on the date of grant and (b) the Exercise Price of any ISO granted to a Ten Percent Stockholder will not be less than one hundred ten percent (110%) of the Fair Market Value of the Shares on the date of grant. Payment for the Shares purchased may be made in accordance with Section 11 and the Award Agreement and in accordance with any procedures established by the Company.

5.5 Method of Exercise. Any Option granted hereunder will be vested and exercisable according to the terms of the Plan and at such times and under such conditions as determined by the Committee and set forth in the Award Agreement. An Option may not be exercised for a fraction of a Share. An Option will be deemed exercised when the Company receives: (a) notice of exercise (in such form as the Committee may specify from time to time) from the person entitled to exercise the Option (and/or via electronic execution through the authorized third-party administrator), and (b) full payment for the Shares with respect to which the Option is exercised (together with applicable withholding taxes). Full payment may consist of any consideration and method of payment authorized by the Committee and permitted by the Award Agreement and the Plan. Shares issued upon exercise of an Option will be issued in the name of the Participant. Until the Shares are issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares, notwithstanding the exercise of the Option. The Company will issue (or cause to be issued) such Shares promptly after the Option is exercised. No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 2.6 of the Plan. Exercising an Option in any manner will decrease the number of Shares thereafter available, both for purposes of the Plan and for sale under the Option, by the number of Shares as to which the Option is exercised.

5.6 Termination of Service. If the Participant’s Service terminates for any reason except for Cause or the Participant’s death or Disability, then the Participant may exercise such Participant’s Options only to the extent that such Options would have been exercisable by the Participant on the date Participant’s Service terminates no later than three (3) months after the date Participant’s Service terminates (or such shorter time period not less than thirty

(30) days or longer time period as may be determined by the Committee, with any exercise beyond three (3) months after the date Participant's Service terminates deemed to be the exercise of an NSO), but in any event no later than the expiration date of the Options.

(a) Death. If the Participant's Service terminates because of the Participant's death (or the Participant dies within three (3) months after Participant's Service terminates other than for Cause or because of the Participant's Disability), then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant's legal representative, or authorized assignee, no later than twelve (12) months after the date Participant's Service terminates (or such shorter time period not less than six (6) months or longer time period as may be determined by the Committee), but in any event no later than the expiration date of the Options.

(b) Disability. If the Participant's Service terminates because of the Participant's Disability, then the Participant's Options may be exercised only to the extent that such Options would have been exercisable by the Participant on the date Participant's Service terminates and must be exercised by the Participant (or the Participant's legal representative or authorized assignee) no later than twelve (12) months after the date Participant's Service terminates (or such shorter time period not less than six (6) months or longer time period as may be determined by the Committee, with any exercise beyond (a) three (3) months after the date Participant's Service terminates when the termination of Service is for a Disability that is not a "permanent and total disability" as defined in Section 22(e)(3) of the Code, or (b) twelve (12) months after the date Participant's Service terminates when the termination of Service is for a Disability that is a "permanent and total disability" as defined in Section 22(e)(3) of the Code, deemed to be exercise of an NSO), but in any event no later than the expiration date of the Options.

(c) Cause. If the Participant's Service is terminated for Cause, then Participant's Options shall expire on such Participant's date of termination of Service, or at such later time and on such conditions as are determined by the Committee, but in any event no later than the expiration date of the Options. Unless otherwise provided in an employment agreement or the Award Agreement, Cause shall have the meaning set forth in the Plan.

5.7 Limitations on Exercise. The Committee may specify a minimum number of Shares that may be purchased on any exercise of an Option, provided that such minimum number will not prevent any Participant from exercising the Option for the full number of Shares for which it is then exercisable.

5.8 Limitations on ISOs. With respect to Awards granted as ISOs, to the extent that the aggregate Fair Market Value of the Shares with respect to which such ISOs are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Parent or Subsidiary) exceeds one hundred thousand dollars (\$100,000), such Options will be treated as NSOs. For purposes of this Section 5.8, ISOs will be taken into account in the order in which they were granted. The Fair Market Value of the Shares will be determined as of the time the Option with respect to such Shares is granted. In the event that the Code or the regulations promulgated thereunder are amended after the Effective Date to provide for a different limit on the Fair Market Value of Shares permitted to be subject to ISOs, such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.

5.9 Modification, Extension or Renewal. The Committee may modify, extend or renew outstanding Options and authorize the grant of new Options in substitution therefor, provided that any such action may not, without the written consent of a Participant, impair any of such Participant's rights under any Option previously granted. Any outstanding ISO that is modified, extended, renewed or otherwise altered will be treated in accordance with Section 424(h) of the Code.

5.10 No Disqualification. Notwithstanding any other provision in this Plan, no term of this Plan relating to ISOs will be interpreted, amended or altered, nor will any discretion or authority granted under this Plan be exercised, so as to disqualify this Plan under Section 422 of the Code or, without the consent of the Participant affected, to disqualify any ISO under Section 422 of the Code.

6. RESTRICTED STOCK AWARDS. A Restricted Stock Award is an offer by the Company to sell to an eligible Employee, Consultant, or Director Shares that are subject to restrictions ("*Restricted Stock*"). The Committee will determine to whom an offer will be made, the number of Shares the Participant may purchase, the Purchase Price,

the restrictions under which the Shares will be subject and all other terms and conditions of the Restricted Stock Award, subject to the Plan.

6.1 Restricted Stock Purchase Agreement. All purchases under a Restricted Stock Award will be evidenced by an Award Agreement. Except as may otherwise be provided in an Award Agreement, a Participant accepts a Restricted Stock Award by signing and delivering to the Company an Award Agreement with full payment of the Purchase Price, within thirty (30) days from the date the Award Agreement was delivered to the Participant. If the Participant does not accept such Award within thirty (30) days, then the offer of such Restricted Stock Award will terminate, unless the Committee determines otherwise.

6.2 Purchase Price. The Purchase Price for a Restricted Stock Award will be determined by the Committee and may be less than Fair Market Value on the date the Restricted Stock Award is granted. Payment of the Purchase Price must be made in accordance with Section 11 of the Plan, and the Award Agreement and in accordance with any procedures established by the Company.

6.3 Terms of Restricted Stock Awards. Restricted Stock Awards will be subject to such restrictions as the Committee may impose or are required by law. These restrictions may be based on completion of a specified number of years of service with the Company or upon completion of Performance Factors, if any, during any Performance Period as set out in advance in the Participant's Award Agreement. Prior to the grant of a Restricted Stock Award, the Committee shall: (a) determine the nature, length and starting date of any Performance Period for the Restricted Stock Award; (b) select from among the Performance Factors to be used to measure performance goals, if any; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Restricted Stock Awards that are subject to different Performance Periods and having different performance goals and other criteria.

6.4 Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

7. STOCK BONUS AWARDS. A Stock Bonus Award is an award to an eligible Employee, Consultant, or Director of Shares for Services to be rendered or for past Services already rendered to the Company or any Parent, Subsidiary or Affiliate. All Stock Bonus Awards shall be made pursuant to an Award Agreement. No payment from the Participant will be required for Shares awarded pursuant to a Stock Bonus Award.

7.1. Terms of Stock Bonus Awards. The Committee will determine the number of Shares to be awarded to the Participant under a Stock Bonus Award and any restrictions thereon. These restrictions may be based upon completion of a specified number of years of service with the Company or upon satisfaction of performance goals based on Performance Factors during any Performance Period as set out in advance in the Participant's Stock Bonus Agreement. Prior to the grant of any Stock Bonus Award the Committee shall: (a) determine the nature, length and starting date of any Performance Period for the Stock Bonus Award; (b) select from among the Performance Factors to be used to measure performance goals; and (c) determine the number of Shares that may be awarded to the Participant. Performance Periods may overlap and a Participant may participate simultaneously with respect to Stock Bonus Awards that are subject to different Performance Periods and different performance goals and other criteria.

7.2. Form of Payment to Participant. Payment may be made in the form of cash, whole Shares, or a combination thereof, based on the Fair Market Value of the Shares earned under a Stock Bonus Award on the date of payment, as determined in the sole discretion of the Committee.

7.3. Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

8. STOCK APPRECIATION RIGHTS. A Stock Appreciation Right ("**SAR**") is an award to an eligible Employee, Consultant, or Director that may be settled in cash, or Shares (which may consist of Restricted Stock), having a value equal to (a) the difference between the Fair Market Value on the date of exercise over the Exercise Price multiplied by (b) the number of Shares with respect to which the SAR is being settled (subject to any

maximum number of Shares that may be issuable as specified in an Award Agreement). All SARs shall be made pursuant to an Award Agreement.

8.1 Terms of SARs. The Committee will determine the terms of each SAR including, without limitation: (a) the number of Shares subject to the SAR; (b) the Exercise Price and the time or times during which the SAR may be settled; (c) the consideration to be distributed on settlement of the SAR; and (d) the effect of the Participant's termination of Service on each SAR. The Exercise Price of the SAR will be determined by the Committee when the SAR is granted, and may not be less than Fair Market Value. A SAR may be awarded upon satisfaction of Performance Factors, if any, during any Performance Period as are set out in advance in the Participant's individual Award Agreement. If the SAR is being earned upon the satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for each SAR; and (y) select from among the Performance Factors to be used to measure the performance, if any. Performance Periods may overlap and Participants may participate simultaneously with respect to SARs that are subject to different Performance Factors and other criteria.

8.2 Exercise Period and Expiration Date. A SAR will be exercisable within the times or upon the occurrence of events determined by the Committee and set forth in the Award Agreement governing such SAR. The SAR Agreement shall set forth the expiration date; provided that no SAR will be exercisable after the expiration of ten (10) years from the date the SAR is granted. The Committee may also provide for SARs to become exercisable at one time or from time to time, periodically or otherwise (including, without limitation, upon the attainment during a Performance Period of performance goals based on Performance Factors), in such number of Shares or percentage of the Shares subject to the SAR as the Committee determines. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee). Notwithstanding the foregoing, the rules of Section 5.6 also will apply to SARs.

8.3 Form of Settlement. Upon exercise of a SAR, a Participant will be entitled to receive payment from the Company in an amount determined by multiplying (a) the difference between the Fair Market Value of a Share on the date of exercise over the Exercise Price; times (b) the number of Shares with respect to which the SAR is exercised. At the discretion of the Committee, the payment from the Company for the SAR exercise may be in cash, in Shares of equivalent value, or in some combination thereof. The portion of a SAR being settled may be paid currently or on a deferred basis with such interest or Dividend Equivalent Right, if any, as the Committee determines, provided that the terms of the SAR and any deferral satisfy the requirements of Section 409A of the Code.

8.4 Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

9. RESTRICTED STOCK UNITS A Restricted Stock Unit ("**RSU**") is an award to an eligible Employee, Consultant, or Director covering a number of Shares that may be settled in cash, or by issuance of those Shares (which may consist of Restricted Stock). All RSUs shall be made pursuant to an Award Agreement.

9.1 Terms of RSUs. The Committee will determine the terms of an RSU including, without limitation: (a) the number of Shares subject to the RSU; (b) the time or times during which the RSU may be settled; (c) the consideration to be distributed on settlement; and (d) the effect of the Participant's termination of Service on each RSU; provided that no RSU shall have a term longer than ten (10) years. An RSU may be awarded upon satisfaction of such performance goals based on Performance Factors during any Performance Period as are set out in advance in the Participant's Award Agreement. If the RSU is being earned upon satisfaction of Performance Factors, then the Committee will: (x) determine the nature, length and starting date of any Performance Period for the RSU; (y) select from among the Performance Factors to be used to measure the performance, if any; and (z) determine the number of Shares deemed subject to the RSU. Performance Periods may overlap and participants may participate simultaneously with respect to RSUs that are subject to different Performance Periods and different performance goals and other criteria.

9.2 Form and Timing of Settlement. Payment of earned RSUs shall be made as soon as practicable after the date(s) determined by the Committee and set forth in the Award Agreement. The Committee, in its sole discretion, may settle earned RSUs in cash, Shares, or a combination of both. The Committee may also permit a Participant to

defer payment under a RSU to a date or dates after the RSU is earned provided that the terms of the RSU and any deferral satisfy the requirements of Section 409A of the Code.

9.3 Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on such date Participant's Service terminates (unless determined otherwise by the Committee).

10. PERFORMANCE AWARDS. A Performance Award is an award to an eligible Employee, Consultant, or Director of the Company or any Parent, Subsidiary or Affiliate that is based upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee, and may be settled in cash, Shares (which may consist of, without limitation, Restricted Stock), other property, or any combination thereof. Grants of Performance Awards shall be made pursuant to an Award Agreement that cites Section 10 of the Plan.

10.1 Types of Performance Awards. Performance Awards shall include Performance Shares, Performance Units, and cash-based Awards as set forth in Sections 10.1(a), 10.1(b), and 10.1(c) below.

(a) **Performance Shares.** The Committee may grant Awards of Performance Shares, designate the Participants to whom Performance Shares are to be awarded and determine the number of Performance Shares and the terms and conditions of each such Award.

(b) **Performance Units.** The Committee may grant Awards of Performance Units, designate the Participants to whom Performance Units are to be awarded and determine the number of Performance Units and the terms and conditions of each such Award.

(c) **Cash-Settled Performance Awards.** The Committee may also grant cash-settled Performance Awards to Participants under the terms of this Plan.

The amount to be paid under any Performance Award may be adjusted on the basis of such further consideration as the Committee shall determine in its sole discretion.

10.2 Terms of Performance Awards. Performance Awards will be based on the attainment of performance goals using the Performance Factors within this Plan that are established by the Committee for the relevant Performance Period. The Committee will determine, and each Award Agreement shall set forth, the terms of each Performance Award including, without limitation: (a) the amount of any cash bonus, (b) the number of Shares deemed subject to an award of Performance Shares; (c) the Performance Factors and Performance Period that shall determine the time and extent to which each award of Performance Shares shall be settled; (d) the consideration to be distributed on settlement, and (e) the effect of the Participant's termination of Service on each Performance Award. In establishing Performance Factors and the Performance Period the Committee will: (x) determine the nature, length and starting date of any Performance Period; (y) select from among the Performance Factors to be used; and (z) determine the number of Shares deemed subject to the award of Performance Shares. Each Performance Share will have an initial value equal to the Fair Market Value of a Share on the date of grant. Prior to settlement the Committee shall determine the extent to which Performance Awards have been earned. Performance Periods may overlap and Participants may participate simultaneously with respect to Performance Awards that are subject to different Performance Periods and different performance goals and other criteria.

10.3 Termination of Service. Except as may be set forth in the Participant's Award Agreement, vesting ceases on the date Participant's Service terminates (unless determined otherwise by the Committee).

11. PAYMENT FOR SHARE PURCHASES. Payment from a Participant for Shares purchased pursuant to this Plan may be made in cash or by check or, where approved for the Participant by the Committee and where permitted by law (and to the extent not otherwise set forth in the applicable Award Agreement):

(a) by cancellation of indebtedness of the Company to the Participant;

(b) by surrender of Shares held by the Participant that have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which said Award will be exercised or settled;

(c) by waiver of compensation due or accrued to the Participant for services rendered or to be rendered to the Company or a Parent, Subsidiary or Affiliate;

(d) by consideration received by the Company pursuant to a broker-assisted or other form of cashless exercise program implemented by the Company in connection with the Plan;

(e) by any combination of the foregoing; or

(f) by any other method of payment as is permitted by applicable law.

The Committee may limit the availability of any method of payment, to the extent the Committee determines, in its discretion, that such limitation is necessary or advisable to comply with applicable law or facilitate the administration of the Plan.

12. GRANTS TO NON-EMPLOYEE DIRECTORS. Non-Employee Directors are eligible to receive any type of Award offered under this Plan except ISOs. Awards pursuant to this Section 12 may be automatically made pursuant to policy adopted by the Board, or made from time to time as determined in the discretion of the Board. The aggregate grant date fair value of Awards granted to a Non-Employee Director pursuant to this Section 12 in any calendar year shall not exceed \$500,000, except that the aggregate grant date fair value of Awards granted to a new Non-Employee Director pursuant to this Section 12 in the calendar year in which they commence their service to the Company shall not exceed \$1,000,000.

12.1. Eligibility. Awards pursuant to this Section 12 shall be granted only to Non-Employee Directors. A Non-Employee Director who is elected or re-elected as a member of the Board will be eligible to receive an Award under this Section 12.

12.2. Vesting, Exercisability and Settlement. Except as set forth in Section 21, Awards shall vest, become exercisable and be settled as determined by the Board. With respect to Options and SARs, the exercise price granted to Non-Employee Directors shall not be less than the Fair Market Value of the Shares at the time that such Option or SAR is granted.

12.3. Election to receive Awards in Lieu of Cash. A Non-Employee Director may elect to receive his or her annual retainer payments and/or meeting fees from the Company in the form of cash or Awards or a combination thereof, as determined by the Committee. Such Awards shall be issued under the Plan. An election under this Section 12.3 shall be filed with the Company on the form prescribed by the Company.

13. WITHHOLDING TAXES.

13.1. Withholding Generally. Whenever Shares are to be issued in satisfaction of Awards granted under this Plan or a tax event occurs, the Company may require the Participant to remit to the Company, or to the Parent, Subsidiary or Affiliate, as applicable, to which the Participant provides Service, an amount sufficient to satisfy applicable U.S. federal, state, local and international withholding tax requirements or any other tax or social insurance liability (collectively, "**Tax-Related Items**") legally due from the Participant prior to the delivery of Shares pursuant to exercise or settlement of any Award. Whenever payments in satisfaction of Awards granted under this Plan are to be made in cash, such payment will be net of an amount sufficient to satisfy applicable Tax-Related Items legally due from the Participant. Unless otherwise determined by the Committee, the Fair Market Value of the Shares will be determined as of the date that the taxes are required to be withheld and such Shares shall be valued based on the value of the actual trade or, if there is none, the Fair Market Value of the Shares as of the previous trading day.

13.2. Stock Withholding. The Committee, or its delegate(s), as permitted by applicable law, in its sole discretion and pursuant to such procedures as it may specify from time to time and to limitations of local law, may require or permit a Participant to satisfy such Tax-Related Items legally due from the Participant, in whole or in part by (without limitation) (a) paying cash, (b) electing to have the Company withhold otherwise deliverable cash or

Shares having a Fair Market Value equal to the Tax-Related Items to be withheld, (c) delivering to the Company already-owned Shares having a Fair Market Value equal to the Tax-Related Items to be withheld or (d) withholding from proceeds of the sale of otherwise deliverable Shares acquired pursuant to an Award either through a voluntary sale or through a mandatory sale arranged by the Company. The Company may withhold or account for these Tax-Related Items by considering applicable statutory withholding rates or other applicable withholding rates, including up to the maximum permissible statutory tax rate for the applicable tax jurisdiction, to the extent consistent with applicable laws.

14. TRANSFERABILITY.

14.1. Transfer Generally. Unless determined otherwise by the Committee or pursuant to Section 14.2, an Award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution. If the Committee makes an Award transferable, including, without limitation, by instrument to an inter vivos or testamentary trust in which the Awards are to be passed to beneficiaries upon the death of the trustor (settlor) or by gift or by domestic relations order to a Permitted Transferee, such Award will contain such additional terms and conditions as the Committee deems appropriate. All Awards shall be exercisable: (a) during the Participant's lifetime only by (i) the Participant, or (ii) the Participant's guardian or legal representative; (b) after the Participant's death, by the legal representative of the Participant's heirs or legatees; and (c) in the case of all awards except ISOs, by a Permitted Transferee.

14.2. Award Transfer Program. Notwithstanding any contrary provision of the Plan, the Committee shall have all discretion and authority to determine and implement the terms and conditions of any Award Transfer Program instituted pursuant to this Section 14.2 and shall have the authority to amend the terms of any Award participating, or otherwise eligible to participate in, the Award Transfer Program, including (but not limited to) the authority to (a) amend (including to extend) the expiration date, post-termination exercise period and/or forfeiture conditions of any such Award, (b) amend or remove any provisions of the Award relating to the Award holder's continued Service to the Company or its Parent, Subsidiary, or Affiliate, (c) amend the permissible payment methods with respect to the exercise or purchase of any such Award, (d) amend the adjustments to be implemented in the event of changes in the capitalization and other similar events with respect to such Award, and (e) make such other changes to the terms of such Award as the Committee deems necessary or appropriate in its sole discretion. Notwithstanding anything to the contrary in the Plan, in no event will the Committee have the right to determine and implement the terms and conditions of any Award Transfer Program without stockholder approval.

15. PRIVILEGES OF STOCK OWNERSHIP; RESTRICTIONS ON SHARES

15.1 Voting and Dividends. No Participant will have any of the rights of a stockholder with respect to any Shares until the Shares are issued to the Participant, except for any Dividend Equivalent Rights permitted by an applicable Award Agreement. The Committee may provide that any Dividend Equivalent Rights permitted by an applicable Award Agreement shall be deemed to have been reinvested in additional Shares or otherwise reinvested. After Shares are issued to the Participant, the Participant will be a stockholder and have all the rights of a stockholder with respect to such Shares, including the right to vote and receive all dividends or other distributions made or paid with respect to such Shares; provided, that if such Shares are Restricted Stock, then any new, additional or different securities the Participant may become entitled to receive with respect to such Shares by virtue of a stock dividend, stock split or any other change in the corporate or capital structure of the Company will be subject to the same restrictions as the Restricted Stock; provided, further, that the Participant will have no right to retain such stock dividends or stock distributions with respect to Shares that are repurchased at the Participant's Purchase Price or Exercise Price, as the case may be, pursuant to Section 15.2. However, the Committee, in its discretion, may provide in the Award Agreement evidencing any Award that the Participant shall be entitled to Dividend Equivalent Rights with respect to the payment of cash dividends on Shares underlying an Award during the period beginning on the date the Award is granted and ending, with respect to each Share subject to the Award, on the earlier of the date on which the Award is exercised or settled or the date on which it is forfeited. Such Dividend Equivalent Rights, if any, shall be credited to the Participant in the form of additional whole Shares as of the date of payment of such cash dividends on Shares. Notwithstanding the foregoing, dividends and Dividend Equivalent Rights may accrue with respect to unvested Awards, but will not be paid or issued until such Award is fully vested and the Shares are issued to Participant and such Shares are no longer subject to any vesting requirements or repurchase rights on behalf of the Company.

15.2 Restrictions on Shares. At the discretion of the Committee, the Company may reserve to itself and/or its assignee(s) a right to repurchase (a ***Right of Repurchase***) a portion of any or all Unvested Shares held by a Participant following such Participant's termination of Service at any timewithin ninety (90) days (or such longer or shorter time determined by the Committee) after the later of the date Participant's Service terminates and the date the Participant purchases Shares under this Plan, for cash and/or cancellation of purchase money indebtedness, at the Participant's Purchase Price or Exercise Price, as the case may be.

16. CERTIFICATES. All Shares or other securities whether or not certificated, delivered under this Plan will be subject to such stock transfer orders, legends and other restrictions as the Committee may deem necessary or advisable, including restrictions under any applicable U.S. federal, state or foreign securities law, or any rules, regulations and other requirements of the SEC or any stock exchange or automated quotation system upon which the Shares may be listed or quoted and any non-U.S. exchange controls or securities law restrictions to which the Shares are subject.

17. ESCROW; PLEDGE OF SHARES. To enforce any restrictions on a Participant's Shares, the Committee may require the Participant to deposit all certificates representing Shares, together with stock powers or other instruments of transfer approved by the Committee, appropriately endorsed in blank, with the Company or an agent designated by the Company to hold in escrow until such restrictions have lapsed or terminated, and the Committee may cause a legend or legends referencing such restrictions to be placed on the certificates. Any Participant who is permitted to execute a promissory note as partial or full consideration for the purchase of Shares under this Plan will be required to pledge and deposit with the Company all or part of the Shares so purchased as collateral to secure the payment of the Participant's obligation to the Company under the promissory note; provided, however, that the Committee may require or accept other or additional forms of collateral to secure the payment of such obligation and, in any event, the Company will have full recourse against the Participant under the promissory note notwithstanding any pledge of the Participant's Shares or other collateral. In connection with any pledge of the Shares, the Participant will be required to execute and deliver a written pledge agreement in such form as the Committee will from time to time approve. The Shares purchased with the promissory note may be released from the pledge on a pro rata basis as the promissory note is paid.

18. EXCHANGE AND BUYOUT OF AWARDS. Without prior stockholder approval, the Committee may, with the consent of the respective Participants (unless not required pursuant to Section 5.9 of the Plan), pay cash or issue new Awards in exchange for the surrender and cancellation of any, or all, outstanding Awards.

19. SECURITIES LAW AND OTHER REGULATORY COMPLIANCE. An Award will not be effective unless such Award is in compliance with all applicable U.S. and foreign federal and state securities and exchange control laws, rules and regulations of any governmental body, and the requirements of any stock exchange or automated quotation system upon which the Shares may then be listed or quoted, as they are in effect on the date of grant of the Award and also on the date of exercise or other issuance. Notwithstanding any other provision in this Plan, the Company will have no obligation to issue or deliver certificates for Shares under this Plan prior to: (a) obtaining any approvals from governmental agencies that the Company determines are necessary or advisable; and/or (b) completion of any registration or other qualification of such Shares under any state or federal or foreign law or ruling of any governmental body that the Company determines to be necessary or advisable. The Company will be under no obligation to register the Shares with the SEC or to effect compliance with the registration, qualification or listing requirements of any foreign or state securities laws, exchange control laws, stock exchange or automated quotation system, and the Company will have no liability for any inability or failure to do so.

20. NO OBLIGATION TO EMPLOY. Nothing in this Plan or any Award granted under this Plan will confer or be deemed to confer on any Participant any right to continue in the employ of, or to continue any other relationship with, the Company or any Parent, Subsidiary or Affiliate or limit in any way the right of the Company or any Parent, Subsidiary or Affiliate to terminate Participant's employment or other relationship at any time.

21. CORPORATE TRANSACTIONS.

21.1. Assumption or Replacement of Awards by Successor. In the event that the Company is subject to a Corporate Transaction, outstanding Awards acquired under the Plan shall be subject to the agreement evidencing the Corporate Transaction, which need not treat all outstanding Awards in an identical manner. Such agreement, without

the Participant's consent, shall provide for one or more of the following with respect to all outstanding Awards as of the effective date of such Corporate Transaction:

(a) The continuation of an outstanding Award by the Company (if the Company is the successor entity).

(b) The assumption of an outstanding Award by the successor or acquiring entity (if any) of such Corporate Transaction (or by its parents, if any), which assumption, will be binding on all selected Participants; provided that the exercise price and the number and nature of shares issuable upon exercise of any such option or stock appreciation right, or any award that is subject to Section 409A of the Code, will be adjusted appropriately pursuant to Section 424(a) of the Code and/or Section 409A of the Code, as applicable.

(c) The substitution by the successor or acquiring entity in such Corporate Transaction (or by its parents, if any) of equivalent awards with substantially the same terms for such outstanding Awards (except that the exercise price and the number and nature of shares issuable upon exercise of any such option or stock appreciation right, or any award that is subject to Section 409A of the Code, will be adjusted appropriately pursuant to Section 424(a) of the Code and/or Section 409A of the Code, as applicable).

(d) The full or partial acceleration of exercisability or vesting and accelerated expiration of an outstanding Award and lapse of the Company's right to repurchase or re-acquire shares acquired under an Award or lapse of forfeiture rights with respect to shares acquired under an Award.

(e) The settlement of the full value of such outstanding Award (whether or not then vested or exercisable) in cash, cash equivalents, or securities of the successor entity (or its parent, if any) with a Fair Market Value equal to the required amount, followed by the cancellation of such Awards; provided however, that such Award may be cancelled if such Award has no value, as determined by the Committee, in its discretion. Subject to Section 409A of the Code, such payment may be made in installments and may be deferred until the date or dates the Award would have become exercisable or vested. Such payment may be subject to vesting based on the Participant's continued service, provided that the vesting schedule shall not be less favorable to the Participant than the schedule under which the Award would have become vested or exercisable. For purposes of this Section 21.1(e), the Fair Market Value of any security shall be determined without regard to any vesting conditions that may apply to such security.

(f) The cancellation of outstanding Awards in exchange for no consideration.

The Board shall have full power and authority to assign the Company's right to repurchase or re-acquire or forfeiture rights to such successor or acquiring corporation. In addition, in the event such successor or acquiring corporation (if any) refuses to assume, convert, replace or substitute Awards, as provided above, pursuant to a Corporate Transaction, the Committee will notify the Participant in writing or electronically that such Award will be exercisable for a period of time determined by the Committee in its sole discretion, and such Award will terminate upon the expiration of such period. Awards need not be treated similarly in a Corporate Transaction.

21.2. Assumption of Awards by the Company. The Company, from time to time, also may substitute or assume outstanding awards granted by another company, whether in connection with an acquisition of such other company or otherwise, by either; (a) granting an Award under this Plan in substitution of such other company's award; or (b) assuming such award as if it had been granted under this Plan if the terms of such assumed award could be applied to an Award granted under this Plan. Such substitution or assumption will be permissible if the holder of the substituted or assumed award would have been eligible to be granted an Award under this Plan if the other company had applied the rules of this Plan to such grant. In the event the Company assumes an award granted by another company, the terms and conditions of such award will remain unchanged (except that the Purchase Price or the Exercise Price, as the case may be, and the number and nature of Shares issuable upon exercise or settlement of any such Award will be adjusted appropriately pursuant to Section 424(a) of the Code and/or Section 409A of the Code, as applicable). In the event the Company elects to grant a new Option in substitution rather than assuming an existing option, such new Option may be granted with a similarly adjusted Exercise Price. Substitute Awards shall not be deducted from the number of Shares authorized for grant under the Plan or authorized for grant to a Participant in a calendar year.

21.3 Non-Employee Directors' Awards. Notwithstanding any provision to the contrary herein, in the event of a Corporate Transaction, the vesting of all Awards granted to Non-Employee Directors shall accelerate and such Awards shall become exercisable (as applicable) in full prior to the consummation of such event at such times and on such conditions as the Committee determines.

22. ADOPTION AND STOCKHOLDER APPROVAL. This Plan shall be submitted for the approval of the Company's stockholders, consistent with applicable laws, within twelve (12) months before or after the date this Plan is adopted by the Board.

23. TERM OF PLAN/GOVERNING LAW. Unless earlier terminated as provided herein, this Plan will become effective on the Effective Date and will terminate ten (10) years from the date this Plan is adopted by the Board. This Plan and all Awards granted hereunder shall be governed by and construed in accordance with the laws of the State of Delaware (excluding its conflict of law rules).

24. AMENDMENT OR TERMINATION OF PLAN. The Board may at any time terminate or amend this Plan in any respect, including, without limitation, amendment of any form of Award Agreement or instrument to be executed pursuant to this Plan; provided, however, that the Board will not, without the approval of the stockholders of the Company, amend this Plan in any manner that requires such stockholder approval; provided further, that a Participant's Award shall be governed by the version of this Plan then in effect at the time such Award was granted. No termination or amendment of the Plan shall affect any then-outstanding Award unless expressly provided by the Committee; in any event, no termination or amendment of the Plan or any outstanding Award may adversely affect any then outstanding Award without the consent of the Participant, unless such termination or amendment is necessary to comply with applicable law, regulation or rule.

25. NONEXCLUSIVITY OF THE PLAN. Neither the adoption of this Plan by the Board, the submission of this Plan to the stockholders of the Company for approval, nor any provision of this Plan will be construed as creating any limitations on the power of the Board to adopt such additional compensation arrangements as it may deem desirable, including, without limitation, the granting of stock awards and bonuses otherwise than under this Plan, and such arrangements may be either generally applicable or applicable only in specific cases.

26. INSIDER TRADING POLICY. Each Participant who receives an Award shall comply with any policy adopted by the Company from time to time covering transactions in the Company's securities by Employees, officers and/or directors of the Company.

27. ALL AWARDS SUBJECT TO COMPANY CLAWBACK OR RECOUPMENT POLICY. All Awards shall, subject to applicable law, be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of Participant's employment or other service with the Company that is applicable to executive officers, employees, directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law, may require the cancelation of outstanding Awards and the recoupment of any gains realized with respect to Awards.

28. DEFINITIONS. As used in this Plan, and except as elsewhere defined herein, the following terms will have the following meanings:

28.1. "Affiliate" means any person or entity that directly or indirectly through one or more intermediaries controls, or is controlled by, or is under common control with, the Company, including any general partner, managing member, officer or director of the Company, in each case as of the date on which, or at any time during the period for which, the determination of affiliation is being made. For purposes of this definition, the term "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), as used with respect to any person or entity, means the possession, directly or indirectly, of the power to direct or cause the direction of the management policies of such person or entity, whether through the ownership of voting securities or by contract or otherwise.

28.2 "Award" means any award under the Plan, including any Option, Restricted Stock, Stock Bonus, Stock Appreciation Right, Restricted Stock Unit or award of Performance Shares.

28.3 “Award Agreement” means, with respect to each Award, the written or electronic agreement between the Company and the Participant setting forth the terms and conditions of the Award, and country-specific appendix thereto for grants to non-U.S. Participants, which shall be in substantially a form (which need not be the same for each Participant) that the Committee (or in the case of Award agreements that are not used for Insiders, the Committee’s delegate(s)) has from time to time approved, and will comply with and be subject to the terms and conditions of this Plan.

28.4 “Award Transfer Program” means any program instituted by the Committee which would permit Participants the opportunity to transfer any outstanding Awards to a financial institution or other person or entity approved by the Committee.

28.5 “Board” means the Board of Directors of the Company.

28.6 “Cause” means (i) Participant’s willful failure substantially to perform his or her duties and responsibilities to the Company or deliberate violation of a Company policy; (ii) Participant’s commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to the Company; (iii) unauthorized use or disclosure by Participant of any proprietary information or trade secrets of the Company or any other party to whom the Participant owes an obligation of nondisclosure as a result of his or her relationship with the Company; or (iv) Participant’s willful breach of any of his or her obligations under any written agreement or covenant with the Company. The determination as to whether a Participant’s Service is being terminated for Cause shall be made in good faith by the Company and shall be final and binding on the Participant. The foregoing definition does not in any way limit the Company’s ability to terminate a Participant’s employment or consulting relationship at any time as provided in Section 20 above, and the term “Company” will be interpreted to include any Subsidiary or Parent, as appropriate. Notwithstanding the foregoing, the foregoing definition of “Cause” may, in part or in whole, be modified or replaced in each individual employment agreement or Award Agreement with any Participant, provided that such document supersedes the definition provided in this Section 28.6.

28.7 “Code” means the United States Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

28.8 “Committee” means the Compensation Committee of the Board or those persons to whom administration of the Plan, or part of the Plan, has been delegated as permitted by law.

28.9 “Common Stock” means the common stock of the Company.

28.10 “Company” means Achieve Life Sciences, Inc., or any successor corporation.

28.11 “Consultant” means any natural person, including an advisor or independent contractor, engaged by the Company or a Parent, Subsidiary or Affiliate to render services to such entity.

28.12 “Corporate Transaction” means the occurrence of any of the following events:

- (a) any “Person” (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the “beneficial owner” (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company’s then-outstanding voting securities; provided, however, that for purposes of this subclause (a) the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Corporate Transaction;
 - (b) the consummation of the sale or disposition by the Company of all or substantially all of the Company’s assets;
 - (c) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being
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converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation;

(d) any other transaction which qualifies as a “corporate transaction” under Section 424(a) of the Code wherein the stockholders of the Company give up all of their equity interest in the Company (except for the acquisition, sale or transfer of all or substantially all of the outstanding shares of the capital stock of the Company) or

(e) a change in the effective control of the Company that occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purpose of this subclause (e), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Corporate Transaction.

For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company. Notwithstanding the foregoing, to the extent that any amount constituting deferred compensation (as defined in Section 409A of the Code) would become payable under this Plan by reason of a Corporate Transaction, such amount shall become payable only if the event constituting a Corporate Transaction would also qualify as a change in ownership or effective control of the Company or a change in the ownership of a substantial portion of the assets of the Company, each as defined within the meaning of Code Section 409A, as it has been and may be amended from time to time, and any proposed or final Treasury Regulations and IRS guidance that has been promulgated or may be promulgated thereunder from time to time.

28.13. “Director” means a member of the Board.

28.14. “Dividend Equivalent Right” means the right of a Participant, granted at the discretion of the Committee or as otherwise provided by the Plan, to receive a credit for the account of such Participant in an amount equal to the cash, stock or other property dividends in amounts equal equivalent to cash, stock or other property dividends for each Share represented by an Award held by such Participant.

28.15. “Disability” means in the case of incentive stock options, total and permanent disability as defined in Section 22(e)(3) of the Code and in the case of other Awards, that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months.

28.16. “Effective Date” means the date on which this Plan is adopted by the Board.

28.17. “Employee” means any person, including Officers and Directors, employed by the Company or any Parent, Subsidiary or Affiliate. Neither service as a Director nor payment of a director’s fee by the Company will be sufficient to constitute “employment” by the Company.

28.18. “Exchange Act” means the United States Securities Exchange Act of 1934, as amended.

28.19. “Exchange Program” means a program pursuant to which outstanding Awards are surrendered, cancelled or exchanged for cash, the same type of Award or a different Award (or combination thereof).

28.20. “Exercise Price” means, with respect to an Option, the price at which a holder may purchase the Shares issuable upon exercise of an Option and with respect to a SAR, the price at which the SAR is granted to the holder thereof.

28.21. “Fair Market Value” means, as of any date, the value of a share of the Company’s Common Stock determined as follows:

(a) if such Common Stock is publicly traded and is then listed on a national securities exchange, its closing price on the date of determination on the principal national securities exchange on which the Common Stock is listed or admitted to trading as reported in *The Wall Street Journal* or such other source as the Committee deems reliable;

(b) if such Common Stock is publicly traded but is neither listed nor admitted to trading on a national securities exchange, the average of the closing bid and asked prices on the date of determination as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; or

(c) if none of the foregoing is applicable, by the Board or the Committee in good faith.

28.22. “Insider” means an officer or director of the Company or any other person whose transactions in the Company’s Common Stock are subject to Section 16 of the Exchange Act.

28.23. “IRS” means the United States Internal Revenue Service.

28.24. “Non-Employee Director” means a Director who is not an Employee of the Company or any Parent, Subsidiary or Affiliate.

28.25. “Option” means an award of an option to purchase Shares pursuant to Section 5.

28.26. “Parent” means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company if each of such corporations other than the Company owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

28.27. “Participant” means a person who holds an Award under this Plan.

28.28. “Performance Award” means an award covering cash, Shares or other property granted pursuant to Section 10 or Section 12 of the Plan.

28.29. “Performance Factors” means any of the factors selected by the Committee and specified in an Award Agreement, from among the following objective measures, either individually, alternatively or in any combination, applied to the Company as a whole or any business unit or Subsidiary, either individually, alternatively, or in any combination, on a GAAP or non-GAAP basis, and measured, to the extent applicable on an absolute basis or relative to a pre-established target, to determine whether the performance goals established by the Committee with respect to applicable Awards have been satisfied:

(a) Profit Before Tax;

(b) Sales;

(c) Expenses;

(d) Billings;

(e) Revenue

(f) Net revenue;

(g) Earnings (which may include earnings before interest and taxes, earnings before taxes, net earnings, stock-based compensation expenses, depreciation and amortization);

(h) Operating income;

(i) Operating margin;

- (j) Operating profit;
 - (k) Controllable operating profit, or net operating profit;
 - (l) Net profit;
 - (m) Gross margin;
 - (n) Operating expenses or operating expenses as a percentage of revenue;
 - (o) Net income;
 - (p) Earnings per share;
 - (q) Total stockholder return;
 - (r) Market share;
 - (s) Return on assets or net assets;
 - (t) The Company's stock price;
 - (u) Growth in stockholder value relative to a pre-determined index;
 - (v) Return on equity;
 - (w) Return on invested capital;
 - (x) Cash Flow (including free cash flow or operating cash flows);
 - (y) Balance of cash, cash equivalents and marketable securities;
 - (z) Cash conversion cycle;
 - (aa) Economic value added;
 - (bb) Individual confidential business objectives;
 - (cc) Contract awards or backlog;
 - (dd) Overhead or other expense reduction;
 - (ee) Credit rating;
 - (ff) Completion of an identified special project;
 - (gg) Completion of a joint venture or other corporate transaction;
 - (hh) Strategic plan development and implementation;
 - (ii) Succession plan development and implementation;
 - (jj) Improvement in workforce diversity;
 - (kk) Employee satisfaction;
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- (ll) Employee retention;
- (mm) Customer indicators and/or satisfaction;
- (nn) New product invention or innovation;
- (oo) Research and development expenses;
- (pp) Attainment of research and development milestones;
- (qq) Improvements in productivity;
- (rr) Bookings;
- (ss) Working-capital targets and changes in working capital;
- (tt) Attainment of objective operating goals and employee metrics; and
- (uu) Any other metric that is capable of measurement as determined by the Committee.

The Committee may, in recognition of unusual or non-recurring items such as acquisition-related activities or changes in applicable accounting rules, provide for one or more equitable adjustments (based on objective standards) to the Performance Factors to preserve the Committee's original intent regarding the Performance Factors at the time of the initial award grant. It is within the sole discretion of the Committee to make or not make any such equitable adjustments.

28.30. "Performance Period" means one or more periods of time, which may be of varying and overlapping durations, as the Committee may select, over which the attainment of one or more Performance Factors will be measured for the purpose of determining a Participant's right to, and the payment of, a Performance Award.

28.31. "Performance Share" means an Award granted pursuant to Section 10 or Section 12 of the Plan, consisting of a unit valued by reference to a designated number of Shares, the value of which may be paid to the Participant by delivery of Shares or, if set forth in the instrument evidencing the Award, of such property as the Committee shall determine, including, without limitation, cash, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee.

28.32. "Performance Unit" means an Award granted pursuant to Section 10 or Section 12 of the Plan, consisting of a unit valued by reference to a designated amount of property other than Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including, without limitation, cash, Shares, other property, or any combination thereof, upon the attainment of performance goals, as established by the Committee, and other terms and conditions specified by the Committee.

28.33. "Permitted Transferee" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law (including adoptive relationships) of the Employee, any person sharing the Employee's household (other than a tenant or employee), a trust in which these persons (or the Employee) have more than 50% of the beneficial interest, a foundation in which these persons (or the Employee) control the management of assets, and any other entity in which these persons (or the Employee) own more than 50% of the voting interests.

28.34. "Plan" means this Achieve Life Sciences, Inc., 2018 Equity Incentive Plan.

28.35. "Purchase Price" means the price to be paid for Shares acquired under the Plan, other than Shares acquired upon exercise of an Option or SAR.

28.36. “*Restricted Stock Award*” means an award of Shares pursuant to Section 6 or Section 12 of the Plan, or issued pursuant to the early exercise of an Option.

28.37. “*Restricted Stock Unit*” means an Award granted pursuant to Section 9 or Section 12 of the Plan.

28.38. “*SEC*” means the United States Securities and Exchange Commission.

28.39. “*Securities Act*” means the United States Securities Act of 1933, as amended.

28.40. “*Service*” shall mean service as an Employee, Consultant, Director or Non-Employee Director, to the Company or a Parent, Subsidiary or Affiliate, subject to such further limitations as may be set forth in the Plan or the applicable Award Agreement. An Employee will not be deemed to have ceased to provide Service in the case of (a) sick leave, (b) military leave, or (c) any other leave of absence approved by the Company; provided, that such leave is for a period of not more than 90 days (x) unless reemployment upon the expiration of such leave is guaranteed by contract or statute, or (y) unless provided otherwise pursuant to formal policy adopted from time to time by the Company’s Board and issued and promulgated to employees in writing. In the case of any Employee on an approved leave of absence or a reduction in hours worked (for illustrative purposes only, a change in schedule from that of full-time to part-time), the Committee may make such provisions respecting suspension of or modification to vesting of the Award while on leave from the employ of the Company or a Parent, Subsidiary or Affiliate or during such change in working hours as it may deem appropriate, except that in no event may an Award be exercised after the expiration of the term set forth in the applicable Award Agreement. In the event of military or other protected leave, if required by applicable laws, vesting shall continue for the longest period that vesting continues under any other statutory or Company approved leave of absence and, upon a Participant’s returning from such leave (under conditions that would entitle him or her to protection upon such return under the Uniform Services Employment and Reemployment Rights Act or other applicable law), he or she shall be given vesting credit with respect to Awards to the same extent as would have applied had the Participant continued to provide Service to the Company throughout the leave on the same terms as he or she was providing Service immediately prior to such leave. An employee shall have terminated employment as of the date he or she ceases to provide Service (regardless of whether the termination is in breach of local employment laws or is later found to be invalid) and employment shall not be extended by any notice period or garden leave mandated by local law, *provided, however*, that a change in status from an employee to a consultant or advisor shall not terminate the service provider’s Service, unless determined by the Committee, in its discretion. The Committee will have sole discretion to determine whether a Participant has ceased to provide Service and the effective date on which the Participant ceased to provide Service.

28.41. “*Shares*” means shares of Common Stock and the common stock of any successor entity.

28.42. “*Stock Appreciation Right*” means an Award granted pursuant to Section 8 or Section 12 of the Plan.

28.43. “*Stock Bonus*” means an Award granted pursuant to Section 7 or Section 12 of the Plan.

28.44. “*Subsidiary*” means any corporation (other than the Company) in an unbroken chain of corporations beginning with the Company if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

28.45. “*Treasury Regulations*” means regulations promulgated by the United States Treasury Department.

28.46. “*Unvested Shares*” means Shares that have not yet vested or are subject to a right of repurchase in favor of the Company (or any successor thereto).

You understand that your employment or consulting relationship with the Company or a Parent, Subsidiary or Affiliate is for an unspecified duration, can be terminated at any time, and that nothing in this Notice of Grant, the Option Agreement or the Plan changes the nature of that relationship. By accepting this Option, you and the Company agree that this Option is granted under and governed by the terms and conditions of the Plan, this Notice of Grant and the Option Agreement. By accepting this Option, you consent to the electronic delivery and acceptance as further set forth in the Option Agreement.

PARTICIPANT

By:
Name:

ACHIEVE LIFE SCIENCES, INC.

By:
Name:
Title:

**STOCK OPTION AGREEMENT
ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN**

You have been granted an Option by Achieve Life Sciences, Inc. (the “*Company*”), under the 2018 Equity Incentive Plan (the “*Plan*”) to purchase Shares (the “*Option*”), subject to the terms, restrictions and conditions of the Plan, the Notice of Stock Option Grant (the “*Notice of Grant*”) and this Stock Option Agreement, including any special terms and conditions for your country set forth in the appendix attached hereto (the “*Appendix*”) (collectively, the “*Agreement*”).

1. Grant of Option. You have been granted the Option for the number of Shares set forth in the Notice of Grant at the Exercise Price per Share set forth in the Notice of Grant. In the event of a conflict between the terms and conditions of the Plan and the terms and conditions of this Agreement, the terms and conditions of the Plan shall prevail.

If designated in the Notice of Grant as an Incentive Stock Option (“*ISO*”), this Option is intended to qualify as an Incentive Stock Option under Section 422 of the Code. However, if this Option is intended to be an ISO, to the extent that it exceeds the \$100,000 limit under Code Section 422(d), it shall be treated as a Nonqualified Stock Option (“*NSO*”).

2. Termination.

(a)General Rule. If your Service terminates for any reason except death or Disability, and other than for Cause, then this Option will expire at the close of business at Company headquarters on the date three months after your termination of Service (subject to the expiration detailed in Section 6). If your Service is terminated for Cause, this Option will expire upon the date of such termination.

You acknowledge and agree that the vesting schedule set forth in the Notice of Grant may change prospectively in the event that your service status changes between full and part-time status in accordance with Company policies relating to work schedules and vesting of awards. You acknowledge that the vesting of the Shares pursuant to this Agreement is earned only by continuing Service.

(b)Death; Disability. If you die before your Service terminates (or you die within three months of your termination of Service other than for Cause), then this Option will expire at the close of business at Company headquarters on the date 12 months after the date of death (subject to the expiration detailed in Section 6). If your Service terminates because of your Disability, then this Option will expire at the close of business at Company headquarters on the date 12 months after your termination date (subject to the expiration detailed in Section 6).

(c)Termination Date. For purposes of this Option, your Service will be considered terminated as of the date you are no longer actively providing services to the Company or a Parent, Subsidiary or Affiliate (regardless of the reason for such termination and whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or consulting agreement, if any), and your period of

Service will not include any contractual notice period or any period of “garden leave” or similar period mandated under labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or consulting agreement, if any. The Committee shall have the exclusive discretion to determine when you are no longer actively providing services for purposes of this Option (including whether you may still be considered to be providing services while on a leave of absence).

(d)No Notice. You are responsible for keeping track of these exercise periods following your termination of Service for any reason. The Company will not provide further notice of such periods. In no event shall this Option be exercised later than the Expiration Date set forth in the Notice of Grant.

3.Exercise of Option.

(a)Right to Exercise. This Option is exercisable during its term in accordance with the vesting schedule set forth in the Notice of Grant and the applicable provisions of the Plan and this Agreement. In the event of your death, Disability, or other cessation of Service, the exercisability of the Option is governed by the applicable provisions of the Plan, the Notice of Grant and this Agreement. This Option may not be exercised for a fraction of a Share.

(b)Method of Exercise. This Option is exercisable by delivery of an exercise notice in a form specified by the Company (the “*Exercise Notice*”), which shall state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the “*Exercised Shares*”), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice shall be delivered in person, by mail, via electronic mail or facsimile or by other authorized method to the Secretary of the Company or other person designated by the Company. The Exercise Notice shall be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares. This Option shall be deemed to be exercised upon receipt by the Company of a fully executed Exercise Notice accompanied by the aggregate Exercise Price and any applicable withholding of Tax-Related Items as detailed in Section 8 below.

(c)Exercise by Another. If another person wants to exercise this Option after it has been transferred to him or her in compliance with this Agreement, that person must prove to the Company’s satisfaction that he or she is entitled to exercise this Option. That person must also complete the proper Exercise Notice form (as described above) and pay the Exercise Price (as described below) and any applicable withholding of Tax-Related Items as described below.

4.Method of Payment. Payment of the aggregate Exercise Price shall be by any of the following, or a combination thereof, at your election:

(a)your personal check, wire transfer, or a cashier’s check;

(b)for U.S. taxpayers only: certificates for shares of Company stock that you own, along with any forms needed to effect a transfer of those shares to the Company; the value of the shares, determined as of the effective date of the Option exercise, will be applied to the Exercise Price. Instead of surrendering shares of Company stock, you may attest to the ownership of those shares on a form provided by the Company and have the same number of shares subtracted

from the Exercised Shares issued to you. However, you may not surrender, or attest to the ownership of, shares of Company stock in payment of the Exercise Price of your Option if your action would cause the Company to recognize compensation expense (or additional compensation expense) with respect to this Option for financial reporting purposes;

(c) cashless exercise through irrevocable directions to a securities broker approved by the Company to sell all or part of the Exercised Shares and to deliver to the Company from the sale proceeds an amount sufficient to pay the Exercise Price and any withholding of Tax-Related Items. The balance of the sale proceeds, if any, will be delivered to you. The directions must be given by signing a special notice of exercise form provided by the Company; or

(d) other method authorized by the Company.

5. Non-Transferability of Option. In general, except as provided below, only you may exercise this Option prior to your death. You may not transfer or assign this Option, except as provided below. For instance, you may not sell this Option or use it as security for a loan. If you attempt to do any of these things, this Option will immediately become invalid.

However, if you are a U.S. taxpayer, you may dispose of this Option in your will or in a beneficiary designation. If you are a U.S. taxpayer and this Option is designated as a NSO in the Notice of Grant, then the Committee may, in its sole discretion, allow you to transfer this Option as a gift to one or more family members. For purposes of this Agreement, “family member” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law (including adoptive relationships), any individual sharing your household (other than a tenant or employee), a trust in which one or more of these individuals have more than 50% of the beneficial interest, a foundation in which you or one or more of these persons control the management of assets, and any entity in which you or one or more of these persons own more than 50% of the voting interest. In addition, if you are a U.S. taxpayer and this Option is designated as a NSO in the Notice of Grant, then the Committee may, in its sole discretion, allow you to transfer this Option to your spouse or former spouse pursuant to a domestic relations order in settlement of marital property rights. The Committee will allow you to transfer this Option only if both you and the transferee(s) execute the forms prescribed by the Committee, which include the consent of the transferee(s) to be bound by this Agreement.

This Option may not be transferred in any manner other than by will or by the laws of descent or distribution or court order and may be exercised during the lifetime of you only by you, your guardian, or legal representative, as permitted in the Plan and applicable local laws. The terms of the Plan and this Agreement shall be binding upon the executors, administrators, heirs, successors and assigns of you.

6. Term of Option. This Option shall in any event expire on the expiration date set forth in the Notice of Grant, which date is ten years after the grant date (five years after the grant date if this Option is designated as an ISO in the Notice of Grant and Section 5.3 of the Plan applies).

7. Tax Consequences. You should consult a tax adviser for tax consequences relating to this Option in the jurisdiction in which you are subject to tax. **YOU SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.**

(a) Exercising the Option. You will not be allowed to exercise this Option unless you make arrangements acceptable to the Company to pay any withholding of Tax-Related Items.

(b) Notice of Disqualifying Disposition of ISO Shares. If you sell or otherwise dispose of any of the Shares acquired pursuant to an ISO on or before the later of (i) two years after the grant date, or (ii) one year after the exercise date, you shall immediately notify the Company in writing of such disposition. You agree that you may be subject to income tax withholding by the Company on the compensation income recognized from such early disposition of ISO Shares by payment in cash or out of the current compensation paid to you.

8. Responsibility for Taxes. Regardless of any action the Company or, if different, your actual employer (the “*Employer*”) takes with respect to any or all income tax, social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related withholding (“*Tax-Related Items*”), you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of this Option, including the grant, vesting or exercise of this Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (2) do not commit to structure the terms of the grant or any aspect of this Option to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to exercise of the Option, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Item withholding and payment on account obligations of the Company and/or the Employer. In this regard, you authorize the Company and/or the Employer, and their respective agents, at their discretion, to withhold all applicable Tax-Related Items legally payable by you from your wages or other cash compensation paid to you by the Company and/or the Employer. With the Company’s consent, these arrangements may also include, if permissible under local law, (a) withholding Shares that otherwise would be issued to you when you exercise this Option, provided that the Company only withholds the amount of Shares necessary to satisfy the minimum statutory withholding amount, (b) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf and pursuant to this authorization), (c) your payment of a cash amount, or (d) any other arrangement approved by the Company; all under such rules as may be established by the Committee and in compliance with the Company’s Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided, however, that if you are a Section 16 officer of the Company under the Exchange Act, then the Committee (as constituted in accordance with Rule 16b-3 under the Exchange Act) shall establish the method of withholding from alternatives (a)-(d) above, and the Committee shall establish the method prior to the taxable or withholding event. The Fair Market

Value of these Shares, determined as of the effective date of the Option exercise, will be applied as a credit against the Tax-Related Items.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Shares equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, you are deemed to have been issued the full number of Shares subject to the vested RSUs, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items.

Finally, you agree to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or your purchase of Shares that cannot be satisfied by the means previously described. You acknowledge that the Company has no obligation to deliver Shares to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section.

9. Nature of Grant. In accepting this Option, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of this Option is voluntary and occasional and does not create any contractual or other right to receive future grants of stock options, or benefits in lieu of stock options, even if stock options have been granted in the past;

(c) all decisions with respect to future stock options or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) this Option and any Shares acquired under the Plan, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) this Option and any Shares acquired under the Plan, and the income and value of same, are not part of normal or expected compensation for purpose of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement benefits or payments or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company, this Option and any Shares acquired under the Plan, and the income and value of same, are not granted as consideration for, or in connection with, any Service you may provide as a director of any Parent, Subsidiary or Affiliate;

with certainty; (h)the future value of the Shares underlying this Option is unknown, indeterminable, and cannot be predicted

(i)if the underlying Shares do not increase in value, this Option will have no value;

(j)if you exercise this Option and acquire Shares, the value of such Shares may increase or decrease in value, even below the Exercise Price;

(k)no claim or entitlement to compensation or damages shall arise from forfeiture of this Option resulting from the termination of your Service (for any reason whatsoever, whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or engaged or the terms of your employment or service agreement, if any), and in consideration of the grant of this Option to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer or any Parent, Subsidiary or Affiliate, waive your ability, if any, to bring any such claim, and release the Company, the Employer or any Parent, Subsidiary or Affiliate from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, you shall be deemed irrevocably to have agreed not to pursue such claim and agree to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

(l)if you are providing Service outside the United States, neither the Employer, the Company nor any Parent, Subsidiary or Affiliate shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of this Option or of any amounts due to you pursuant to the exercise of this Option or the subsequent sale of any Shares acquired upon exercise.

10.Data Privacy. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this Agreement and any other Option grant materials by and among, as applicable, the Employer, the Company and any Parent, Subsidiary or Affiliate for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares or directorships held in the Company, details of all stock options or any other entitlement to shares awarded, canceled, exercised, vested, unvested or outstanding in your favor (“*Data*”), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to third parties in connection with the implementation, administration and management of the Plan. You understand that the recipients of Data may be located in the United States or elsewhere, and that the recipient’s country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that if you reside outside the United States, he or she may request a list with the names and addresses of any potential recipients of Data by contacting your local human resources representative. You authorize the Company and any other possible recipients which may assist

the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purposes of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that if you reside outside the United States, you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your Service status and career with the Employer will not be adversely affected; the only consequence of refusing or withdrawing your consent is that Company would not be able to grant you stock options or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

11. Acknowledgement. The Company and you agree that this Option is granted under and governed by the Notice of Grant, this Agreement and the provisions of the Plan (incorporated herein by reference). You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that you have carefully read and are familiar with the provisions in the grant documents, and (iii) hereby accept this Option subject to all of the terms and conditions set forth in this Agreement and those set forth in the Plan and the Notice of Grant. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice of Grant and this Agreement.

12. Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures. By your acceptance of this Option, you consent to the electronic delivery of the Notice of Grant, this Agreement, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its stockholders (including, without limitation, annual reports and proxy statements) or other communications or information related to this Option. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at [insert email]. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. You agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at [insert email]. Finally, you understand that you are not required to consent to electronic delivery.

13. Compliance with Laws and Regulations. The exercise of this Option will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer, which compliance the Company shall, in its absolute discretion, deem necessary or advisable. You understand that the Company is under no obligation to register or qualify the Common Stock with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, you agree that the Company shall have unilateral authority to amend the Plan and this Agreement without your consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

14. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

15. Governing Law; Venue. This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice of Grant and this Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in the courts of California in San Diego County, California or the federal courts of the United States for the Southern District of California and no other courts.

16. Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this Agreement, (ii) the balance of this Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this Agreement shall be enforceable in accordance with its terms.

17. No Rights as Employee, Director or Consultant. Nothing in this Agreement shall affect in any manner whatsoever the right or power of the Company, or a Parent, Subsidiary or Affiliate of the Company, to terminate your Service, for any reason, with or without Cause.

18. Adjustment. In the event of a stock split, a stock dividend or a similar change in Company stock, the number of Shares covered by this Option and the Exercise Price per Share may be adjusted pursuant to the Plan.

19. Lock-Up Agreement. In connection with the initial public offering of the Company's securities and upon request of the Company or the underwriters managing any underwritten offering of the Company's securities, you hereby agree not to sell, make any short sale of, loan, grant any Option for the purchase of, or otherwise dispose of any securities of the

Company however and whenever acquired (other than those included in the registration) without the prior written consent of the Company or such underwriters, as the case may be, for such period of time (not to exceed one hundred eighty (180) days) from the effective date of such registration as may be requested by the Company or such managing underwriters and to execute an agreement reflecting the foregoing as may be requested by the underwriters at the time of the public offering; provided however that, if during the last seventeen (17) days of the restricted period the Company issues an earnings release or material news or a material event relating to the Company occurs, or prior to the expiration of the restricted period the Company announces that it will release earnings results during the sixteen (16)-day period beginning on the last day of the restricted period, then, upon the request of the managing underwriter, to the extent required by any FINRA rules, the restrictions imposed by this Section shall continue to apply until the end of the third trading day following the expiration of the fifteen (15)-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. In no event will the restricted period extend beyond two hundred sixteen (216) days after the effective date of the registration statement.

20. Award Subject to Company Clawback or Recoupment. To the extent permitted by applicable law, the Option shall be subject to clawback or recoupment pursuant to any clawback or recoupment policy adopted by the Board or required by law during the term of your employment or other Service that is applicable to you. In addition to any other remedies available under such policy, applicable law may require the cancellation of your Option (whether vested or unvested) and the recoupment of any gains realized with respect to your Option.

21. Entire Agreement; Enforcement of Rights. This Agreement, the Plan and the Notice of Grant constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning this Option are superseded. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, shall be effective unless in writing and signed by the parties to this Agreement. The failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of any rights of such party.

22. Insider Trading Restrictions/Market Abuse Laws. You acknowledge that you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell the Shares or rights to Shares under the Plan during such times as you are considered to have “inside information” regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

23. Language. If you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

24. Appendix. Notwithstanding any provisions in this Agreement, this Option shall be subject to any special terms and conditions set forth in any Appendix hereto for your country.

Moreover, if you relocate to one of the countries included in the Appendix, the special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

25.Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on this Option and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

26.Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other Participant.

BY ACCEPTING THIS OPTION, YOU AGREE TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

APPENDIX

**ADDITIONAL TERMS AND CONDITIONS TO
STOCK OPTION AGREEMENT
ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN**

Capitalized terms, unless explicitly defined in this Appendix, shall have the meanings given to them in the Stock Option Agreement, the Notice of Grant or in the Plan.

Terms and Conditions

This Appendix includes special terms and conditions that govern this Option if you reside and/or work in one of the countries listed below. If you are a citizen or resident (or are considered as such for local law purposes) of a country other than the country in which you are currently residing and/or working, or if you transfer to another country after receiving this Option, the Company shall, in its discretion, determine to what extent the special terms and conditions contained herein shall be applicable to you.

Notifications

This Appendix also includes information regarding securities, exchange control, tax and certain other issues of which you should be aware with respect to your participation in the Plan. The information is based on the securities, exchange control, tax and other laws in effect in the respective countries as of October 2017. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information contained herein as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you exercise this Option or at the time you sell any Shares acquired under the Plan. In addition, the information is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of any particular result. Therefore, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your individual situation.

If you are a citizen or resident (or are considered as such for local tax purposes) of a country other than the country in which you are currently residing and/or working, or if you transfer to another country after the grant of this Option, the information contained herein may not be applicable to you in the same manner.

CANADA

Terms and Conditions

Manner of Exercising Option.

Due to regulatory requirements, you are prohibited from surrendering certificates for Shares that you already own to pay the Exercise Price or any Tax-Related Items in connection with the exercise of your Shares.

You hereby authorize the Company and the Company's representatives to discuss with and obtain all relevant information from all personnel, professional or not, involved in the administration and operation of the Plan. You further authorize the Employer, the Company and Parent, Subsidiaries and Affiliates and the administrator of the Plan to disclose and discuss the Plan with their advisors. You further authorize the Employer to record such information and to keep such information in your employee file.

Language Consent

The following provisions will apply if you are a resident of Quebec:

The parties acknowledge that it is their express wish that this Agreement, as well as all documents, notices and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de cette convention ("Agreement"), ainsi que de tous documents exécutés, avis donnés et procédures judiciaires intentées, directement ou indirectement, relativement à la présente convention.

UNITED KINGDOM

Terms and Conditions

Data privacy

The following provision replaces Section 10 of the Global Stock Option Grant Agreement:

To the satisfaction and on the direction of the Committee, all operations of the Plan and this Option (at the time of its grant and as necessary thereafter) shall include or be supported by appropriate agreements, notifications and arrangements in respect of Data and its use and processing under the Plan, in order to secure:

- (a) the reasonable freedom of the Employer, the Company and any Parent or Subsidiary (together, the "**Group**"), as appropriate, to operate the Plan and for connected purposes; and
 - (b) compliance with the data protection requirements applicable from time to time, including, without limitation:
 - (aa) the Data Protection Act 1998;
 - (bb) Regulation EU 2016/679 of the European Parliament and of the Council of 27 April 2016 (the "**GDPR**"); and
-

(cc) the Group's relevant policies and practices.

The above shall include, and other provision may also be made as the Committee decides:

- (a) the collection, use, processing and transfer of your Data by any member of the Group or any Affiliate or third parties in connection with the implementation, administration and management of the Plan;
- (b) the transfer of your Data amongst themselves by members of the Group or any Affiliate or third parties in connection with the implementation, administration and management of the Plan;
- (c) the use of such Data by any such person for any appropriate purpose; and
- (d) as reasonably necessary, the transfer to and retention of your Data by third parties in connection with the implementation, administration and management of the Plan (whether or not any such third party is situated outside the European Economic Area) for or in connection with any appropriate purpose, on such terms and by such means as may be required by applicable data protection law and guidance.

A data privacy notice, in a form approved by the Committee, setting out applicable provisions in respect of Data, and any related information or disclosure that may be required or appropriate, [was provided to you on [DATE]] / [accompanies this Option Agreement and you acknowledge receipt of that notice]. Further information, disclosures or other measures in respect of Data and your participation in the Plan may be notified to you in future, as may be required.

"Data" for these purposes includes, but is not limited to your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares or directorships held in the Company, details of all stock options or any other entitlement to shares awarded, canceled, exercised, vested, unvested or outstanding in your favor and any other personal information which could identify you.

Responsibility for Taxes.

The following provision supplements Section 8 of the Global Stock Option Agreement:

If payment or withholding of the income tax is due in connection with the Option and is not made within ninety (90) days after the end of the year in which the event giving rise to the income tax liability occurs or such other period specified in Section 222(1)(c) of the ITEPA 2003 (the "**Due Date**"), the amount of any uncollected income tax will constitute a loan owed by you to the Employer, effective on the Due Date. You agree that the loan will bear interest at then-current Official Rate of Her Majesty's Revenue and Customs ("**HMRC**"), it will be immediately due and repayable, and the Company or the Employer may recover it at any time thereafter by any of the means referred to in the Agreement.

Notwithstanding the foregoing, if you are a director or executive officer of the Company (within the meaning of Section 13(k) of the U.S. Securities Exchange Act of 1934, as amended), you will not be eligible for such a loan to cover the income tax due as described above. In the event that you are a director or executive officer and the income tax is not collected from or paid by you by the Due Date, the amount of any uncollected tax will constitute a benefit to you on which additional income tax and National Insurance Contributions (“**NICs**”) will be payable. You acknowledge that the Company or the Employer may recover any such additional income tax and NICs at any time thereafter by any of the means referred to in the Agreement. You will also be responsible for reporting and paying any income tax and NICs due on this additional benefit directly to HMRC under the self-assessment regime.

Employer NICs.

As a condition of participation in the Plan, you agree and undertake to the Company and to the Employer to accept any liability for secondary Class 1 National Insurance Contributions that may be payable by the Company or the Employer (or any successor to the Company or the Employer) in connection with the Option and any event giving rise to Tax-Related Items (the “**Employer NICs**”). The Employer NICs may be collected by the Company or the Employer using any of the methods described in the Plan or in Section 8 of the Global Stock Option Agreement.

You further agree, if required to do so, to execute a joint election with the Company and/or the Employer (a “**Joint Election**”), the form of such Joint Election being formally approved by HMRC, and any other consent or elections required by the Company or the Employer in respect of the Employer NICs liability. You further agree to execute such other elections as may be required by any successor to the Company and/or the Employer for the purpose of continuing the effectiveness of your Joint Election.

* * *

**NOTICE OF RESTRICTED STOCK UNIT AWARD
(UNITED STATES, CANADA, UNITED KINGDOM)**

**ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN
GRANT NUMBER:**

Unless otherwise defined herein, the terms defined in the Achieve Life Sciences, Inc. (the “*Company*”), 2018 Equity Incentive Plan (the “*Plan*”) shall have the same meanings in this Notice of Restricted Stock Unit Award (the “*Notice*”) and the attached Award Agreement (Restricted Stock Unit Agreement, including any special terms and conditions for your country set forth in the appendix attached thereto (collectively, the “*RSU Agreement*”). You (“*you*”) have been granted an award of Restricted Stock Units (“*RSUs*”) under the Plan subject to the terms and conditions of the Plan, this Notice and the attached RSU Agreement.

Name:

Address:

Number of RSUs:

Date of Grant:

Vesting Commencement Date:

Expiration Date:

The settlement of all vested RSUs granted hereunder. The RSUs expire earlier if your Service terminates earlier, as described in the RSU Agreement.

Vesting Schedule:

[Sample vesting language:] [25% of the total number of RSUs will vest on the twelve month anniversary of the Vesting Commencement Date and 25% of the total number of RSUs will vest on each annual anniversary thereafter so long as your Service continues.][Note: actual vesting language to match vesting schedule approved by the Board or Committee]

Additional Terms:

If your address set forth above is an address located outside the United States, the additional terms and conditions set forth on an Appendix attached hereto (as executed by the Company) are applicable and are incorporated herein by reference. (No Appendix need be attached if your address set forth above is an address located within the United States.)

(Signature page follows.)

You acknowledge that the vesting of the RSUs pursuant to this Notice is earned only by continuing Service. By accepting this award, you and the Company agree that this award is granted under and governed by the terms and conditions of the Plan, this Notice and the RSU Agreement. By accepting this award of RSUs, you consent to the electronic delivery and acceptance as further set forth in the RSU Agreement.

PARTICIPANT

By:
Name:

ACHIEVE LIFE SCIENCES, INC.

By:
Name:
Title:

RESTRICTED STOCK UNIT AGREEMENT
ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN

You have been granted Restricted Stock Units (“*RSUs*”) by Achieve Life Sciences, Inc. (the “*Company*”), subject to the terms, restrictions and conditions of the Plan, the Notice of Restricted Stock Unit Award (the “*Notice*”) and this Restricted Stock Unit Agreement, including any special terms and conditions for your country set forth in the appendix attached hereto (the “*Appendix*”) (collectively, this “*RSU Agreement*”).

1. Nature of Grant. In accepting this award of RSUs, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the grant of the RSUs is voluntary and occasional and does not create any contractual or other right to receive future awards of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) unless otherwise agreed with the Company, the RSUs and any Shares acquired under the Plan, and the income and value of same, are not granted as consideration for, or in connection with, any service you may provide as a director of the Company, or a Parent or Subsidiary of the Company;

(h) the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

(i) no claim or entitlement to compensation or damages shall arise from forfeiture of the RSUs resulting from the termination of your Service (for any reason whatsoever whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are providing Service or the terms of your employment or service agreement, if any), and in consideration of the grant of the RSUs to which you are otherwise not entitled, you irrevocably agree never to institute any claim against the Company, the Employer (as defined below), or any other Parent or

Subsidiary of the Company, waive your ability, if any, to bring any such claim, and release the Company, the Employer and its Parent or Subsidiaries from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by participating in the Plan, you shall be deemed irrevocably to have agreed not to pursue such claim and agree to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

(j) the following provisions apply only if you are providing Service outside the United States:

(i) the RSUs and the Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation or salary for any purpose; and

(ii) neither the Company, the Employer nor any Parent or Subsidiary of the Company shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the RSUs or the subsequent sale of any Shares acquired upon settlement.

2. Settlement. Settlement of RSUs shall be made in the same calendar year as the applicable date of vesting under the vesting schedule set forth in the Notice; provided, however, that if the vesting date under the vesting schedule set forth in the Notice is in December, then settlement of any RSUs that vest in December shall be within 30 days of vesting. Settlement of RSUs shall be in Shares. Settlement means the delivery to you of the Shares vested under the RSUs. Fractional Shares will not be issued.

3. No Stockholder Rights. Unless and until such time as Shares are issued in settlement of vested RSUs, you shall have no ownership of the Shares allocated to the RSUs and shall have no right to dividends or to vote such Shares.

4. Dividend Equivalents. Dividends, if any (whether in cash or Shares), shall not be credited to you.

5. No Transfer. RSUs may not be sold, assigned, transferred, pledged, hypothecated, or otherwise disposed of in any manner other than by will or by the laws of descent or distribution or court order or unless otherwise permitted by the Committee on a case-by-case basis.

6. Termination. If your Service terminates for any reason, all unvested RSUs shall be forfeited to the Company forthwith, and all rights you have to such RSUs shall immediately terminate, without payment of any consideration to you. For purposes of this award of RSUs, your Service will be considered terminated as of the date you are no longer providing Service (regardless of the reason for such termination and whether or not later found to be invalid or in breach of labor laws in the jurisdiction where you are employed or the terms of your employment or service agreement, if any) and will not be extended by any notice period mandated under local employment laws (*e.g.*, Service would not include a period of “garden leave” or similar period). In case of any dispute as to whether your termination of Service has occurred, the Committee shall have sole discretion to determine whether such termination has occurred (including whether you may still be considered to be providing Services while on a leave of absence) and the effective date of such termination.

7. Tax Consequences. You acknowledge that there will be certain consequences with regard to income tax, national or social insurance contributions, payroll tax, fringe benefits tax, payment on account or other tax-related items (“*Tax-Related Items*”) upon settlement of the RSUs or disposition of the Shares, if any, received in connection therewith, and you should consult a tax adviser regarding your tax obligations prior to such settlement or disposition in the jurisdiction where you are subject to tax.

8. Responsibility for Taxes. Regardless of any action the Company or, if different, your actual employer (the “*Employer*”) takes with respect to any or all Tax-Related Items withholding or required deductions, you acknowledge that the ultimate liability for all Tax-Related Items legally due by you is and remains your responsibility and that the Company and/or the Employer (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the award, including the grant, vesting or settlement of the RSUs, the subsequent sale of Shares acquired pursuant to such settlement and the receipt of any dividends; and (2) do not commit to structure the terms of the award or any aspect of the RSUs to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You acknowledge that if you are subject to Tax-Related Items in more than one jurisdiction, the Company and/or the Employer may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to the settlement of your RSUs, you shall pay or make adequate arrangements satisfactory to the Company and/or the Employer to satisfy all Tax-Related Items withholding and payment on account obligations of the Company and/or the Employer. In this regard, you authorize the Company and/or the Employer, and their respective agents, at their discretion, to withhold all applicable Tax-Related Items legally payable by you from your wages or other cash compensation paid to you by the Company and/or the Employer. With the Company’s consent, these arrangements may also include, if permissible under local law, (a) withholding Shares that otherwise would be issued to you when your RSUs are settled, provided that the Company only withholds the amount of Shares necessary to satisfy the minimum statutory withholding amount, (b) having the Company withhold taxes from the proceeds of the sale of the Shares, either through a voluntary sale or through a mandatory sale arranged by the Company (on your behalf pursuant to this authorization), (c) payment by you of an amount equal to the Tax-Related Items directly by cash, cheque, wire transfer, bank draft or money order payable to the Company, or (d) any other arrangement approved by the Company; all under such rules as may be established by the Committee and in compliance with the Company’s Insider Trading Policy and 10b5-1 Trading Plan Policy, if applicable; provided, however, that if you are a Section 16 officer of the Company under the Exchange Act, then the Committee (as constituted in accordance with Rule 16b-3 under the Exchange Act) shall establish the method of withholding from alternatives (a)-(d) above, and the Committee shall establish the method prior to the taxable or withholding event. The Fair Market Value of these Shares, determined as of the effective date when taxes otherwise would have been withheld in cash, will be applied as a credit against the Tax-Related Items.

Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding rates or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Shares equivalent. If the obligation for Tax-Related Items is satisfied by withholding in Shares, for tax purposes, you are

deemed to have been issued the full number of Shares subject to the vested RSUs, notwithstanding that a number of the Shares are held back solely for the purpose of paying the Tax-Related Items.

Finally, you agree to pay to the Company or the Employer any amount of Tax-Related Items that the Company or the Employer may be required to withhold as a result of your participation in the Plan or the vesting and settlement of the RSUs that cannot be satisfied by the means previously described. You acknowledge that the Company has no obligation to deliver Shares to you until you have satisfied the obligations in connection with the Tax-Related Items as described in this Section.

9.Data Privacy. You hereby explicitly and unambiguously consent to the collection, use and transfer, in electronic or other form, of your personal data as described in this RSU Agreement and any other RSU grant materials by and among, as applicable, the Company, the Employer and any other Parent or Subsidiaries, for the exclusive purpose of implementing, administering and managing your participation in the Plan.

You understand that the Company and the Employer may hold certain personal information about you, including, but not limited to, your name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company, details of all RSUs or any other entitlement to shares of stock awarded, canceled, exercised, vested, unvested or outstanding in your favor ("**Data**"), for the exclusive purpose of implementing, administering and managing the Plan.

You understand that Data will be transferred to the stock plan service provider as may be designated by the Company from time to time, which is assisting the Company with the implementation, administration and management of the Plan. You understand that the recipients of Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than your country. You understand that if you reside outside the United States, you may request a list with the names and addresses of any potential recipients of Data by contacting your local human resources representative. You authorize the Company, the designated broker and any other possible recipients which may assist the Company (presently or in the future) with implementing, administering and managing the Plan to receive, possess, use, retain and transfer Data, in electronic or other form, for the sole purpose of implementing, administering and managing your participation in the Plan. You understand that Data will be held only as long as is necessary to implement, administer and manage your participation in the Plan. You understand that if you reside outside the United States, you may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing your local human resources representative. Further, you understand that you are providing the consents herein on a purely voluntary basis. If you do not consent, or if you later seek to revoke your consent, your employment status or service and career with the Employer will not be adversely affected. The only adverse consequence of refusing or withdrawing your consent is that the Company would not be able to grant you RSUs or other equity awards or administer or maintain such awards. Therefore, you understand that refusing or withdrawing your consent may affect your ability to participate in the Plan. For more information on the consequences of your refusal to consent or withdrawal of consent, you understand that you may contact your local human resources representative.

10. Acknowledgement. The Company and you agree that the RSUs are granted under and governed by the Notice, this RSU Agreement and the provisions of the Plan. You: (i) acknowledge receipt of a copy of the Plan prospectus, (ii) represent that you have carefully read and are familiar with the provisions in the grant documents, and (iii) hereby accept the RSUs subject to all of the terms and conditions set forth in this RSU Agreement and those set forth in the Notice. You hereby agree to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan, the Notice and this RSU Agreement.

11. Entire Agreement; Enforcement of Rights. This RSU Agreement, the Plan and the Notice constitute the entire agreement and understanding of the parties relating to the subject matter herein and supersede all prior discussions between them. Any prior agreements, commitments or negotiations concerning the purchase of the Shares hereunder are superseded. No modification of or amendment to this RSU Agreement, nor any waiver of any rights under this RSU Agreement, shall be effective unless in writing and signed by the parties to this RSU Agreement. The failure by either party to enforce any rights under this RSU Agreement shall not be construed as a waiver of any rights of such party.

12. Compliance with Laws and Regulations. The issuance of Shares will be subject to and conditioned upon compliance by the Company and you with all applicable state, federal and foreign laws and regulations and with all applicable requirements of any stock exchange or automated quotation system on which the Company's Common Stock may be listed or quoted at the time of such issuance or transfer, which compliance the Company shall, in its absolute discretion, deem necessary or advisable. You understand that the Company is under no obligation to register or qualify the Common Stock with any state, federal or foreign securities commission or to seek approval or clearance from any governmental authority for the issuance or sale of the Shares. Further, you agree that the Company shall have unilateral authority to amend the Plan and this RSU Agreement without your consent to the extent necessary to comply with securities or other laws applicable to issuance of Shares. Finally, the Shares issued pursuant to this RSU Agreement shall be endorsed with appropriate legends, if any, determined by the Company.

13. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

14. Governing Law; Venue. This RSU Agreement, all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts of law. For purposes of litigating any dispute that may arise directly or indirectly from the Plan, the Notice and this RSU Agreement, the parties hereby submit and consent to litigation in the exclusive jurisdiction of the State of California and agree that any such litigation shall be conducted only in the courts of California in San Diego County, California or the federal courts of the United States for the Southern District of California and no other courts.

15. Severability. If one or more provisions of this RSU Agreement are held to be unenforceable under applicable law, the parties agree to renegotiate such provision in good faith. In the event that

the parties cannot reach a mutually agreeable and enforceable replacement for such provision, then (i) such provision shall be excluded from this RSU Agreement, (ii) the balance of this RSU Agreement shall be interpreted as if such provision were so excluded and (iii) the balance of this RSU Agreement shall be enforceable in accordance with its terms.

16.No Rights as Employee, Director or Consultant. Nothing in this RSU Agreement shall affect in any manner whatsoever the right or power of the Company, or a Parent or Subsidiary of the Company, to terminate your Service, for any reason, with or without Cause.

17.Consent to Electronic Delivery and Acceptance of All Plan Documents and Disclosures. By your acceptance of this award of RSUs, you consent to the electronic delivery of the Notice, this RSU Agreement, the Plan, account statements, Plan prospectuses required by the SEC, U.S. financial reports of the Company, and all other documents that the Company is required to deliver to its stockholders (including, without limitation, annual reports and proxy statements) or other communications or information related to the RSUs. Electronic delivery may include the delivery of a link to a Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail or such other delivery determined at the Company's discretion. You acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost if you contact the Company by telephone, through a postal service or electronic mail at [insert email]. You further acknowledge that you will be provided with a paper copy of any documents delivered electronically if electronic delivery fails; similarly, you understand that you must provide on request to the Company or any designated third party a paper copy of any documents delivered electronically if electronic delivery fails. You agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company. Also, you understand that your consent may be revoked or changed, including any change in the electronic mail address to which documents are delivered (if you have provided an electronic mail address), at any time by notifying the Company of such revised or revoked consent by telephone, postal service or electronic mail at [insert email]. Finally, you understand that you are not required to consent to electronic delivery.

18.Insider Trading Restrictions/Market Abuse Laws. You acknowledge that, depending on your country, you may be subject to insider trading restrictions and/or market abuse laws, which may affect your ability to acquire or sell the Shares or rights to Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in your country). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Company insider trading policy. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you are advised to speak to your personal advisor on this matter.

19.Language. If you have received this RSU Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

20.Appendix. Notwithstanding any provisions in this Restricted Stock Unit Agreement, this award of RSUs shall be subject to any special terms and conditions set forth in any Appendix hereto for your country. Moreover, if you relocate to one of the countries included in the Appendix, the

special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this RSU Agreement.

21.Imposition of Other Requirements. The Company reserves the right to impose other requirements on your participation in the Plan, on the RSUs and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

22.Waiver. You acknowledge that a waiver by the Company of breach of any provision of this RSU Agreement shall not operate or be construed as a waiver of any other provision of this RSU Agreement, or of any subsequent breach by you or any other Participant.

23.Code Section 409A. For purposes of this RSU Agreement, a termination of employment will be determined consistent with the rules relating to a “separation from service” as defined in Section 409A of the Code and the regulations thereunder (“**Section 409A**”). Notwithstanding anything else provided herein, to the extent any payments provided under this RSU Agreement in connection with your termination of employment constitute deferred compensation subject to Section 409A, and you are deemed at the time of such termination of employment to be a “specified employee” under Section 409A, then such payment shall not be made or commence until the earlier of (i) the expiration of the six-month period measured from your separation from service from the Company or (ii) the date of your death following such a separation from service; provided, however, that such deferral shall only be effected to the extent required to avoid adverse tax treatment to you including, without limitation, the additional tax for which you would otherwise be liable under Section 409A(a)(1)(B) in the absence of such a deferral. To the extent any payment under this RSU Agreement may be classified as a “short-term deferral” within the meaning of Section 409A, such payment shall be deemed a short-term deferral, even if it may also qualify for an exemption from Section 409A under another provision of Section 409A. Payments pursuant to this section are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

24.Award Subject to Company Clawback or Recoupment. The RSUs shall be subject to clawback or recoupment pursuant to any compensation clawback or recoupment policy adopted by the Board or required by law during the term of your employment or other Service that is applicable to executive officers, Employees, Directors or other service providers of the Company, and in addition to any other remedies available under such policy and applicable law may require the cancellation of your RSUs (whether vested or unvested) and the recoupment of any gains realized with respect to your RSUs.

BY ACCEPTING THIS AWARD OF RSUS, YOU AGREE TO ALL OF THE TERMS AND CONDITIONS DESCRIBED ABOVE AND IN THE PLAN.

APPENDIX

**ADDITIONAL TERMS AND CONDITIONS TO
RESTRICTED STOCK UNIT AGREEMENT
ACHIEVE LIFE SCIENCES, INC.
2018 EQUITY INCENTIVE PLAN**

Capitalized terms, unless explicitly defined in this Appendix, shall have the meanings given to them in the RSU Agreement, the Notice or in the Plan.

Terms and Conditions

This Appendix includes additional terms and conditions that govern the RSUs granted to you under the Plan if you reside in one of the countries listed below. If you are a citizen or resident (or is considered as such for local law purposes) of a country other than the country in which you are currently residing and/or working, or if you transfer to another country after receiving the RSUs, the Company shall, in its discretion, determine to what extent the special terms and conditions contained herein shall be applicable to you.

Notifications

This Appendix also includes information regarding securities, exchange control, tax and certain other issues of which you should be aware with respect to your participation in the Plan. The information is based on the securities, exchange control, tax and other laws in effect in the respective countries as of October 2017. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time that the RSUs vest or you sell Shares acquired under the Plan.

In addition, the information contained herein is general in nature and may not apply to your particular situation and the Company is not in a position to assure you of a particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your individual situation.

Finally, if you are a citizen or resident (or are considered as such for local tax purposes) of a country other than the one in which you are currently residing and/or working, or if you transfer to another country after the grant of the RSUs, the information contained herein may not be applicable to you in the same manner.

CANADA

Terms and Conditions

Settlement.

The following provision supplements Section 2 of the Restricted Stock Unit Agreement: Notwithstanding anything to the contrary in the Plan, including Section 9.2 of the Plan, the RSUs will be settled in Shares only, not cash.

Termination.

The following sentence replaces the second sentence of Section 6 of the Restricted Stock Unit Agreement: For purposes of this award of RSUs, your Service will be considered terminated as of the date that is the earliest to occur of: (1) the date of termination of Service, (2) the date you receive notice of termination from the Employer, and (3) the date you are no longer actively providing services, regardless of any notice period or period of pay in lieu of such notice required under applicable law (including, but not limited to statutory law, regulatory law and/or common law).

Language Consent.

The following provisions will apply to you if you are a resident of Quebec:

The parties acknowledge that it is their express wish that the RSU Agreement, as well as all appendices, documents, notices, and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Les parties reconnaissent avoir exigé la rédaction en anglais de cette Convention, ainsi que de tous documents exécutés, avis donnés et procédures judiciaires intentées, directement ou indirectement, relativement à ou suite à la présente convention.

Data Privacy.

The following provision supplements Section 9 of the Restricted Stock Unit Agreement: You hereby authorize the Company and the Company's representatives to discuss and obtain all relevant information from all personnel, professional or non-professional, involved in the administration of the Plan. You further authorize the Company, the Employer, its Parent or other Subsidiaries and the Committee to disclose and discuss the Plan with their advisors. You further authorize the Company, the Employer and its Parent or other Subsidiary to record such information and to keep such information in your employee file.

Notifications

Securities Law Information.

You are permitted to sell Shares acquired under the Plan through the designated broker appointed under the Plan, if any, provided the sale of the Shares acquired under Plan takes place outside of Canada through the facilities of a stock exchange on which the Common Stock is listed.

Foreign Asset/Account Reporting Information.

Canadian taxpayers must report annually on Form T1135 (Foreign Income Verification Statement) the foreign property (including Shares acquired under the Plan) held if the total value of such foreign property exceeds C\$100,000 at any time during the year. Unvested RSUs also must be reported (generally at nil cost) on Form 1135 if the C\$100,000 threshold is exceeded due to other foreign property held. The Form T1135 must be filed at the same time the individual's files his or her annual tax return. You should consult your personal legal advisor to ensure compliance with applicable reporting obligations.

UNITED KINGDOM

Terms and Conditions

Settlement.

The following provision supplements Section 2 of the Restricted Stock Unit Agreement: Notwithstanding anything to the contrary in the Plan, including Section 9.2 of the Plan, the RSUs will be settled in Shares only, not cash.

Responsibility for Taxes.

The following provision supplements Section 8 of the Restricted Stock Unit Agreement:

You agree that, if you do not pay or the Employer or the Company does not withhold from you the full amount of income tax that you owe at vesting of the RSUs, or the release or assignment of the RSUs for consideration, or the receipt of any other benefit in connection with the RSUs (the "**Taxable Event**") within 90 days of the U.K. tax year within which the Taxable Event occurs, or such other period specified in Section 222(1)(c) of the U.K. Income Tax (Earnings and Pensions) Act 2003 (the "**Due Date**"), then the amount that should have been withheld shall constitute a loan owed by you to the Employer, effective as of the Due Date. You agree that the loan will bear interest at the Her Majesty's Revenue and Customs ("**HMRC**") official rate and will be immediately due and repayable by you, and the Company and/or the Employer may recover it at any time thereafter by any of the means set forth in this Section 8.

Notwithstanding the foregoing, if you are an executive officer or director (as within the meaning of Section 13(k) of the Exchange Act), the terms of the immediately foregoing provision will not apply. In the event that you are an executive officer or director and income tax is not collected from or paid by you by the Due Date, the amount of any uncollected income tax may constitute a benefit to you on which additional income tax and National Insurance contributions ("**NICs**") may be due. You will be responsible for reporting and accounting for any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for reimbursing the Company or the Employer, as applicable, for the value of any NICs due on this additional benefit.

Employer NICs.

As a condition of participation in the Plan, you agree and undertake to the Company and to the Employer to accept any liability for secondary Class 1 National Insurance Contributions that may be payable by the Company or the Employer (or any successor to the Company or the Employer) in connection with the RSUs and any event giving rise to Tax-Related Items (the “**Employer NICs**”). The Employer NICs may be collected by the Company or the Employer using any of the methods described in the Plan or in Section 8 of the Restricted Stock Unit Agreement.

You further agree, if required to do so, to execute a joint election with the Company and/or the Employer (a “**Joint Election**”), the form of such Joint Election being formally approved by HMRC, and any other consent or elections required by the Company or the Employer in respect of the Employer NICs liability. You further agree to execute such other elections as may be required by any successor to the Company and/or the Employer for the purpose of continuing the effectiveness of your Joint Election.

* * *

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 7, 2018

/s/ Richard Stewart

Richard Stewart

Chairman and Chief Executive Officer

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 7, 2018

/s/ John Bencich

John Bencich

Executive Vice President, Chief Financial Officer and Chief Operating Officer

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, 2018 (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 7, 2018

/s/ Richard Stewart

Richard Stewart
Chairman and Chief Executive Officer

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, 2018 (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 7, 2018

/s/ John Bencich

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