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, 2017

or

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

FOR THE TRANSITION PERIOD FROM _____ TO _____.

Commission file number 033-80623

Achieve Life Sciences, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐		Accelerated filer	☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	Smaller reporting company	☒
			Emerging growth company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). 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 9, 2017**
Common Stock, $0.001 par value	11,947,676

Achieve Life Sciences, Inc.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Achieve Life Sciences, Inc.

Consolidated Balance Sheets

(In thousands, except per share and share amounts)

	September 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents *[note 7]*	$ 8,021	$ 15
Amounts receivable	70	—
Prepaid expenses	535	3
Total current assets	**8,626**	**18**
Restricted cash *[note 7 and note 10]*	272	—
Property and equipment, net	94	—
Other assets	415	—
License agreement *[note 2, 4, 5 and 6]*	2,588	2,755
Goodwill *[note 2 and 5]*	1,034	1,034
Total assets	**$ 13,029**	**$ 3,807**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 495	$ 95
Accrued liabilities other	1,297	1,121
Accrued clinical liabilities	162	—
Accrued compensation	343	1,028
Stockholder loans with related parties *[note 9]*	—	829
Current portion of long-term obligations *[note 10]*	31	—
Warrant liability *[note 7 and note 8 [f]]*	3	—
Total current liabilities	**2,331**	**3,073**
Long-term obligations, less current portion *[note 10]*	16	—
Deferred tax liability	—	124
Total liabilities	**2,347**	**3,197**
Commitments and contingencies *[note 10]*		
Stockholders' equity:		
Common stock, $0.001 par value, 75,000,000 shares authorized, 11,491,665 and 21,230 issued at September 30, 2017 and December 31, 2016, respectively, and 11,482,845 and 21,230 outstanding at September 30, 2017 and December 31, 2016, respectively	11	—
Additional paid-in capital	19,581	2,667
Accumulated deficit	(8,915)	(2,062)
Accumulated other comprehensive income	5	5
Total stockholders' equity	**10,682**	**610**
Total liabilities and stockholders' equity	**13,029**	**3,807**
Going concern *[note 1]*		

See accompanying notes.

Achieve Life Sciences, Inc.

Consolidated Statements of Loss and Comprehensive Loss

(Unaudited)

(In thousands, except per share and share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
EXPENSES				
Research and development	825	69	948	206
General and administrative	1,550	329	1,902	899
Total operating expenses	2,375	398	2,850	1,105
OTHER INCOME (EXPENSE)				
Interest income	9	—	9	—
Bargain purchase gain *[note 2]*	1,272	—	1,272	—
Contingent value rights recovery *[note 2]*	200	—	200	—
Gain on warrants	111	—	111	—
Loss on disposition of intangible asset *[note 4]*	(8,610)	—	(8,610)	—
Other expenses	(7)	(7)	(26)	(20)
Total other income (expense)	(7,025)	(7)	(7,044)	(20)
Net loss before income taxes	$ (9,400)	$ (405)	$ (9,894)	$ (1,125)
Recovery of deferred income taxes *[note 4]*	2,928	137	3,051	377
Net loss	(6,472)	(268)	(6,843)	(748)
OTHER COMPREHENSIVE INCOME				
Net unrealized gain on securities	—	—	—	—
Total other comprehensive income	—	—	—	—
Comprehensive loss	$ (6,472)	$ (268)	$ (6,843)	$ (748)
Basic and diluted net loss per common share	$ (0.90)	$ (12.62)	$ (2.81)	$ (35.23)
Shares used in computation of basic and diluted net loss per common share	7,225,826	21,230	2,435,095	21,230

See accompanying notes

Achieve Life Sciences, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2017	**2016**
Operating Activities:		
Net loss	$ (6,843)	$ (748)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on warrants *[note 7 and note 8 [f]]*	(111)	—
Depreciation and amortization *[note 4]*	191	166
Deferred income tax (recovery) *[note 2 and note 4]*	(3,051)	(377)
Non cash (gain) loss on foreign exchange	—	4
Stock-based compensation *[note 8 [c] and note 8 [d]]*	152	—
Bargain purchase gain *[note 2]*	(1,272)	—
Loss on disposition *[note 4]*	8,610	—
Contingent value rights liability recovery *[note 4]*	(200)	—
Changes in operating assets and liabilities:		
Amounts receivable	(164)	—
Prepaid expenses and other assets	(1,597)	(3)
Accounts payable	400	48
Accrued liabilities other	(1,123)	299
Accrued clinical liabilities	162	—
Accrued compensation	(685)	471
Lease obligation	47	—
Net cash used in operating activities	(5,484)	(140)
Financing Activities:		
Proceeds from Loans, net of issuance costs	—	100
Proceeds from purchase agreement with Lincoln Park Capital, net of issuance costs	1,129	—
Taxes paid related to net share settlement of equity awards	(22)	—
Net cash provided by financing activities	1,107	100
Investing Activities:		
Cash received on reverse merger of OncoGenex *[note 2]*	12,376	—
Net cash provided by investing activities	12,376	—
Effect of exchange rate changes on cash	7	—
Net increase (decrease) in cash and cash equivalents	8,006	(40)
Cash and cash equivalents at beginning of period	15	67
Cash and cash equivalents at end of period	$ 8,021	$ 27
Supplemental Disclosure of Cash Flow Information:		
Non cash financing activities		
Non-cash settlement of Stockholder loans with related parties *[note 9]*		

See accompanying notes.

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 committed to the global development and commercialization of cytisine for smoking cessation. We were incorporated in the state of Delaware, and operate out of Vancouver, British Columbia and Bothell, Washington.

On August 2, 2017, OncoGenex Pharmaceuticals, Inc. ("OncoGenex") completed a transaction ("the Arrangement") with Achieve Life Sciences Inc., ("Achieve") whereby OncoGenex acquired all of the outstanding preferred shares, common shares and convertible debentures of Achieve. OncoGenex changed its name to Achieve Life Sciences, Inc. and is listed on the Nasdaq Capital Market under the ticker symbol ACHV. These consolidated financial statements account for the Arrangement between OncoGenex and Achieve as a reverse merger, whereby Achieve is deemed to be the acquiring entity from an accounting perspective. The consolidated results of operations include our results of operations for the full three and nine months ended September 30, 2017 and the results of OncoGenex following the completion of the Arrangement on August 1, 2017. The consolidated results of operations for the three and nine months ended September 31, 2016 include only our consolidated results of operations and do not include historical results of OncoGenex.

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, 2016 has been derived from the audited consolidated financial statements included in our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the Securities and Exchange Commission, or SEC, on June 6, 2017. 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 Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC on June 6, 2017.

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 $8.9 million through September 30, 2017. During the nine months ended September 30, 2017, we incurred a net loss of $6.8 million. As of September 30, 2017, we had a cash and cash equivalents balance of $8.0 million and a positive working capital balance of $6.3 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 from alternative sources. 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) and equity financing (Note 8—Common Stock). Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

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, including raising additional financing through our purchase agreement and financing with Lincoln Park Capital (See Purchase Agreement and Financing with Lincoln Park Capital" under Note 8—Common Stock) and other sources. 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 our results of operations for the full three and nine months ended September 30, 2017 and the results of OncoGenex following the completion of the Arrangement on August 1, 2017. The consolidated results of operations for the three and nine months ended September 30, 2016 include only our consolidated results of operations and do not include historical results of OncoGenex.

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. All information in the financial statements and the notes thereto relating to the number of shares, price per share, and per share amounts of common stock are presented on a post-split basis.

Under the purchase method of accounting, OncoGenex's outstanding shares of common stock were valued using the closing price on NASDAQ of $4.62 as at August 1, 2017. There were 2,736,703 shares of common stock outstanding, as adjusted for the reverse stock split, 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 $4.62, 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 $4.62, 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		2,736,709
Multiplied by the price per share of OncoGenex stock	$	4.62
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	$	13,050

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	(1,272)
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 issued for each share of their common stock outstanding as of the record date for such issuance. Each CVR is a non-transferable right to potentially receive certain cash, equity or other consideration received by us in the event that we receive 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 apatorsen, 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, if any, will be 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. Under the CVR Agreement, for a period of six months beginning in February 2017, we will use certain defined efforts to enter into an agreement with a third party regarding the development and/or commercialization of apatorsen. At the expiration of this six-month period, if a third party has not entered into a term sheet for the development or commercialization of apatorsen, we will no longer be contractually required to pursue an agreement regarding apatorsen and no consideration will be payable to the holders of CVRs.

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 apatorsen. A recovery of $0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ 5,062
Net loss applicable to common shareholders	$ (9,730)	$ (4,197)	$ (10,100)	$ (15,034)
Net loss per share-basic and diluted	$ (1.35)	$ (0.14)	$ (4.15)	$ (0.50)
Weighted average shares	7,225,826	30,013,928	2,435,095	29,925,479

3. ACCOUNTING POLICIES

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, 2018 and interim periods within that year. This standard is expected to have a significant impact on our current accounting for our lease arrangements, particularly our current operating lease arrangements, as well as our disclosures. We are currently evaluating the impact of adoption on our financial position and results from operations.

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 are currently in the process of evaluating the impact of adoption of ASU No. 2014-09 and cannot reasonably estimate how the adoption of the standard will impact our consolidated financial statements and related disclosures.

Recently Adopted Accounting Policies

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.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The standard requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. Entities are currently required to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. The amendments, which require non-current presentation only (by jurisdiction), are effective for financial statements issued for annual periods beginning after December 15, 2016 with earlier application permitted as of the beginning of an interim or annual reporting period. The guidance is to be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The adoption of this standard did not have a significant impact on our financial position or results of operations.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810) — Amendments to the Consolidation Analysis. ASU 2015-02 eliminates the deferral of FAS 167 and makes changes to both the variable interest model and the voting model. For public business entities, the guidance is effective for annual and interim periods beginning after 15 December 2015. For nonpublic business entities, it is effective for annual periods beginning after 15 December 2016, and interim periods beginning after 15 December 2017. 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, notifying them that we have discontinued development of apatorsen resulting in termination of the license agreement related to this product candidate. We intend to also terminate the University of British Columbia, or UBC, license agreement related to apatorsen provided that Ionis does not exercise its reversion rights within 90 days of the notice of discontinuance. If Ionis exercises its reversion rights related to apatorsen, we believe Ionis will assume the rights and obligations under the UBC license agreement. 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 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 acquired license and supply agreements, in relation to cytisine, 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 (Note 5— Extab Acquisition).

The components of intangible assets were as follows:

	September 30, 2017			December 31, 2016		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
License Agreements	$ 3,117	$ (529)	$ 2,588	$ 3,117	$ (362)	$ 2,755

For the three and nine months ended September 30, 2017 we recorded license agreement amortization expenseof $0.1 million and $0.2 million, respectively. For the three and nine months ended September 30, 2016 we recorded license agreement amortization expense of $0.1 million and $0.2 million, respectively. The following table outlines the estimated future amortization expense related to intangible assets held as of September 30, 2017:

Year Ending December 31,	
2017	56
2018	223
2019	223
2020	223
2021	223
Thereafter	1,640
Total	**$ 2,588**

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 cytisine, and concluded no impairment has occurred as of September 30, 2017.

5. EXTAB ACQUISITION

On May 14, 2015, we entered into a Share Purchase Agreement with Sopharma, AD, or Sopharma, a public pharmaceutical company located in Bulgaria, to acquire 75% of the outstanding shares of Extab.

Pursuant to the Share Purchase Agreement, we acquired a 75% controlling interest in Extab from Sopharma for $2.0 million in cash and $2.0 million in a deferred payment, contingent on regulatory approval of cytisine by the Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA. In addition, as part of and in conjunction with the Share Purchase Agreement, we amended our existing license and supply agreements with Sopharma, extending their terms by five years and reducing the royalty rate payable by us. (Note 6—License Agreements) Subsequent to the acquisition, we paid to Sopharma $0.3 million to retire the balance of Extab's outstanding loans with Sopharma.

The acquisition was accounted for using the acquisition method under ASC 805 business combinations. Results of operations have been included in the financial statements from the date of acquisition May 18, 2015, the date we assumed control of Extab. The fair value of the business combination was determined using level 3 inputs.

The purchase price of Achieve's 75% controlling interest in Extab was as follows:

	Fair Value
Cash consideration	$ 2,000
Contingent consideration	—
Purchase Price	**$ 2,000**

As of the date of acquisition we assessed the likelihood of meeting the contingent event as unlikely and as a result have estimated its fair value at zero. We consider the best indicator of the fair value of net assets acquired to be the $2.0 million cash consideration paid to acquire Achieve's 75% controlling interest plus the $0.7 million fair value attributable to the non-controlling interest, or NCI, calculated on a proportionate basis.

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities of Extab based on their estimated fair values as of the transaction closing date. The allocation of the purchase price based on the estimated fair values is as follows:

	Fair Value
Cash	$ 6
License agreements	$ 3,117
Goodwill	$ 1,034
Other current liabilities	$ (456)
Deferred tax liability	$ (1,034)
Non-controlling interest	$ (667)
	$ 2,000

The license agreement expires May 26, 2029. As of the acquisition date, we estimated its useful life to be the same as the remaining 14 year contractual life. We also elected to amortize intangible assets on a straight line basis over its useful life, since there is no pattern of successful economic benefits available at the time to reliably determine a different amortization.

Subsequent to acquiring control of Extab, we entered into an agreement with the NCI stockholder of Extab to convert their shares in Extab into shares of our common stock. As of September 30, 2015, all of the NCI had converted their shares in Extab into shares of our common stock resulting in elimination of the Extab non-controlling interest and Extab becoming a wholly-owned subsidiary of us.

6. 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 cytisine, as well as a granted patent in several European countries including Germany, France and Italy related to new oral dosage forms of cytisine 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, we have paid Sopharma $10 pursuant to the Sopharma License Agreement.

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 cytisine from Sopharma, and Sopharma agrees to exclusively supply all such cytisine requested by us, and we extended the term to 2037. In addition, Achieve will have full access to the cytisine supply chain and Sopharma will manufacture sufficient cytisine to meet a forecast for a specified demand of cytisine 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 cytisine and its derivatives for use in smoking cessation, including a number of patent applications related to novel approaches to cytisine 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.

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 cytisine to the University of Bristol as an initial contribution. To date, we have paid the University of Bristol $50,000 pursuant to the University of Bristol License Agreement.

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, notifying them that we have discontinued development of apatorsen resulting in termination of the license agreement related to this product candidate. We intend to also terminate the University of British Columbia, or UBC, license agreement related to apatorsen provided that Ionis does not exercise its reversion rights within 90 days of the notice of discontinuance. If Ionis exercises its reversion rights related to apatorsen, we believe Ionis will assume the rights and obligations under the UBC license agreement. 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.

7. 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, 2017, we recorded a $3,000 warrant liability. 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 shares of our common stock 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, 2017	Level 1	Level 2	Level 3	Total
Assets				
Cash	$ 3,010	$ —	$ —	$ 3,010
Money market securities (cash equivalents)	5,011	—	—	5,011
Restricted cash (Note 7)	272	—	—	272
Total assets	**$ 8,293**	**$ —**	**$ —**	**$ 8,293**
Liabilities				
Warrants	$ —	$ —	$ 3	$ 3

The following table presents the changes in fair value of our total Level 3 financial liabilities for the nine months ended September 30, 2017. During the nine months ended September 30, 2017, we did not issue any common stock warrants that were classified as liabilities (in thousands):

	Liability at December 31, 2016	Liability Assumed as part of Arrangement	Unrealized Gain on warrants	Liability at September 30, 2017
Warrant liability	$ —	$ 114	$ (111)	$ 3

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

September 30, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash	$ 3,010	$ —	$ —	$ 3,010
Money market securities	5,011	—	—	5,011
Total cash and cash equivalents	**$ 8,021**	**$ —**	**$ —**	**$ 8,021**
Money market securities (restricted cash)	272	—	—	272
Total restricted cash	**$ 272**	**$ —**	**$ —**	**$ 272**

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, 2017 and 2016.

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.

8. COMMON STOCK

[a] Authorized

75,000,000 authorized common shares, par value of $0.001, and 5,000,000 preferred shares, par value of $0.001.

[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.

Pursuant to the Purchase Agreement, LPC initially purchased 328,947 of our units, or the Units, at a purchase price of $3.04 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 $3.496 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 80,000 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 $2.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 123,516 shares of common stock; no cash proceeds were received from the issuance of these shares.

From September 14, 2017 through September 30, 2017, we offered and sold 408,947 shares of our common stock pursuant to our Purchase Agreement with LPC, including the 328,947 shares that were part of the initial purchase of Units. These sales resulted in gross proceeds to us of approximately $1.2 million and offering expenses of $0.1 million. As of September 30, 2017 shares of our common stock having an aggregate value of approximately $9.8 million remained available for sale under this offering program.

Equity Award Issuances and Settlements

During the nine months ended September 30, 2017, we issued no shares of common stock to satisfy stock option exercises and 3,548 shares of common stock to satisfy restricted stock unit settlements, compared with the issuance of no shares of common stock to satisfy stock option exercises and no shares of common stock to satisfy restricted stock unit settlements, respectively, during the nine months ended September 30, 2016.

[c] Stock options

2017 Equity Incentive Plan

As of September 30, 2017, we had reserved, pursuant to the 2017 Equity Incentive Plan, or the 2017 Plan, 1,052,200 common shares for issuance upon exercise of stock options, currently outstanding, by employees, directors and officers of ours.

Under the 2017 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 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, 2017, we had reserved, pursuant to the 2010 Performance Incentive Plan, or the 2010 Plan, 304,323 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 93,907 were reserved for options currently outstanding and 210,416 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, 2016	**—**	**$ —**
Additions from OncoGenex Plans	113,451	92.61
Granted	1,052,200	2.89
Expired	(19,544)	114.53
Forfeited	—	—
Balance, September 30, 2017	**1,146,107**	**$ 9.87**

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. For the nine months ended September 30, 2017, the weighted-average assumptions used in the Black-Scholes option-pricing model are noted in the following table. No stock options were granted during the nine months ended September 30, 2016:

	Nine Months Ended September 30, 2017
Risk-free interest rates	1.95%
Expected dividend yield	0%
Expected life	6.00
Expected volatility	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 reverse merger of OncoGenex. 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,	
	2017	2016	2017	2016
Research and development	$ 43	$ —	$ 43	$ —
General and administrative	$ 109	—	109	—
Total stock-based compensation	$ 152	$ —	$ 152	$ —

As of September 30, 2017 and December 31, 2016, the total unrecognized compensation expense related to stock options granted was $2.1 million and zero, respectively, which is expected to be recognized as expense over a period of approximately 3.9 years from September 30, 2017.

For the three and nine months ended September 30, 2017, a total of 1.7 million shares, consisting of 0.4 million warrants, 1.1 million options and 0.2 million 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 period in 2016, we had no shares underlying options, restricted stock units or warrants.

[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, 2017, we recorded a compensation expense of $0.1 million and $0.1 million, respectively, related to these awards. No restricted stock awards were granted during 2016.

The following table summarizes our restricted stock unit award activity during the nine months ended September 30, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance, December 31, 2016	—	**$** —
Additions from OncoGenex Plans	10,543	41.14
Granted	205,100	2.89
Released	(5,208)	44.36
Forfeited or expired	(19)	51.91
Balance, September 30, 2017	**210,416**	**$ 3.78**

As of September 30, 2017, we had approximately $0.6 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 4.0 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, 2017:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	252,721	44.000	July 2019
(2) Series B Warrants issued in July 2014 financing	60,933	44.000	July 2019
(3) Series A-1 Warrants issued in April 2015 financing	21,748	26.400	October 2020
(4) Warrants issued in September 2017 financing	82,237	3.496	March 2023

No warrants were exercised during the nine months ended September 30, 2017 or 2016. The Series A-1 Warrants assumed by us as part of the Arrangement and the warrants issued in the September 2017 financing are classified as equity. The Series A and Series B 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.

Series A and Series B Warrant Valuation Assumptions	As of September 30, 2017
Risk-free interest rates	1.42%
Expected dividend yield	0%
Expected life	1.75 years
Expected volatility	86.06%

9. RELATED PARTY TRANSACTION

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, 359.3053 shares of OncoGenex's common stock, or 170,670 shares of common stock post-conversion. As of September 30, 2017 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, 359.3014 shares of OncoGenex's common stock, or 52,458 shares of common stock post-conversion As of September 30, 2017 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, 359.3052 shares of OncoGenex's common stock, or 1,827,426 shares of common stock post-conversion. As of September 30, 2017 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 will make a payment in cash for the remaining 50%. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 359.3025 shares of OncoGenex's common stock, or 85,514 shares of common stock post-conversion. As of September 30, 2017 we accrued $0.3 million in accrued liabilities on our balance sheet for the remaining 50% of the payment to be paid as cash.

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 will make a payment in cash for the remaining 50%. Pursuant to the terms of the Arrangement, each share was converted into, approximately, 359.2992 shares of OncoGenex's common stock, or 45,631 shares of common stock post-conversion. As of September 30, 2017 we accrued $0.2 million in accrued liabilities on our balance sheet for the remaining 50% of the separation payment to be paid as cash

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, 2017.

10. COMMITMENTS AND CONTINGENCIES

The following table summarizes our contractual obligations as of September 30, 2017 (in thousands):

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Bothell office operating lease	$ 167	$ 167	$ —	$ —	$ —
Vancouver office operating lease	$ 98	$ 98	$ —	$ —	$ —
Leased equipment	$ 13	$ 13	$ —	$ —	$ —
Total	**$ 278**	**$ 278**	**$ —**	**$ —**	**$ —**

Lease Arrangements

We have an operating lease agreement for office space being used in Vancouver, Canada, which expires in September 2018. 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):

2017	25
2018	73
Total	**$ 98**

In February 2015, we entered into an office lease with Grosvenor International (Atlantic Freeholds) Limited, or Landlord, pursuant to which we leased approximately 11,526 square feet located at 19820 North Creek Parkway, Bothell, Washington, 98011, commencing on February 15, 2015. The initial term of this lease will expire on April 30, 2018, with an option to extend the term for one approximately three-year period. Our monthly base rent for the premises will start at approximately $18,000 commencing on May 1, 2015 and will increase on an annual basis up to approximately $20,000. We received a construction allowance, for leasehold improvements that we made, of approximately $0.1 million. We will be responsible for 17% of taxes levied upon the building during each calendar year of the term. We delivered to the Landlord a letter of credit in the amount of $0.2 million, in accordance with the terms if the lease, which the Landlord may draw upon for base rent or other damages in the event of our default under this lease. In August 2015 we exercised our expansion option for an additional 2,245 square feet of office space, which commenced on August 1, 2015.

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

2017	71
2018	96
Total	**$ 167**

Consolidated rent and operating expense relating to both the Vancouver, Canada and Bothell, Washington offices for the three and nine months ended September 30, 2017 was $0.1 million and $0.1 million, respectively. There was no rent related expense in 2016.

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, 2017.

We have certain agreements with certain organizations with which we do business that contain indemnification provisions pursuant to which we typically agrees 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.

11. 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, 2017.

12. SUBSEQUENT EVENTS

From October 1, 2017 through November 9, 2017, we offered and sold 464,831 shares of our common stock pursuant to our Purchase Agreement with LPC. These sales resulted in gross proceeds to us of approximately $0.9 million. As of November 9, 2017 shares of our common stock having an aggregate value of approximately $8.9 million remained available for sale under this offering program.

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

INFORMATION REGARDING FORWARD LOOKING STATEMENTS

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

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

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.

Arrangement Agreement

As discussed in the notes to the financial statements above, during 2017, we completed the Arrangement with OncoGenex. For more information concerning the Arrangement, see the discussion of the Arrangement in Note 2 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisine for smoking cessation. Our focus is to address the global smoking health epidemic, which is the leading cause of preventable death and is responsible for nearly six million deaths annually worldwide.

Cytisine is an established 25 day smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by a third party for over 20 years under the brand name Tabex™. As of December 2016, it is estimated that over 21 million people have used cytisine to help combat 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.

Cytisine is a naturally occurring, plant-based alkaloid from the seeds of the*Laburnum anagyroides* plant. Cytisine 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 cytisine dosing schedule reflects that of an anti-addiction medication, with downward dose titration over a period of 25 days.

We have met with the United States Food and Drug Administration, or FDA, and with other national regulatory authorities in Europe to identify the steps required for the approval of cytisine. The FDA requested results from non-clinical studies, additional human pharmacokinetic studies and adequate demonstration of safety and efficacy from randomized, placebo-controlled, Phase 3 clinical trials.

The non-clinical studies requested by the FDA have been sponsored and completed by the National Center for Complementary and Integrative Health, or NCCIH, division of the U.S. National Institutes of Health, in addition to the National Cancer Institute. In July 2017, we filed our Investigational New Drug, or IND, application for cytisine with the FDA, which included NCCIH sponsored non-clinical studies. The IND was accepted in August 2017.

In August 2017, we initiated a study evaluating the effect of food on the bioavailability of cytisine in normal healthy volunteers. We have recently completed the food effect study and expect data by the end of 2017. In October 2017, we initiated a study assessing the repeat-dose pharmacokinetic and pharmacodynamic effects of cytisine in smokers. We expect data from this repeat-dose study in the first quarter of 2018.

We intend to hold a pre-Phase 3 meeting with the FDA in the first quarter of 2018 to review our Phase 3 program and overall development plans for cytisine. We intend to commence a Phase 3 clinical program in mid-2018, subject to FDA guidance and the availability of capital. In addition to the Phase 3 program, we expect to run additional supportive studies including, but not limited to, drug to drug interaction, renal impairment, hepatic impairment, carcinogenicity, and QT interval prolongation.

While third party trials of cytisine have been conducted that may inform future Company-sponsored clinical trials, we have not yet conducted any large scale clinical trials for cytisine in the United States or any other jurisdiction.

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

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 $6.8 million for the nine months ended September 30, 2017, and $0.7 million for the nine months ended September 30, 2016. As of September 30, 2017, we had an accumulated deficit of $8.9 million, cash and cash equivalents balance of $8.0 million and a positive working capital balance of $6.3 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 from alternative sources. 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, cytisine and add personnel necessary to operate as a public company with an advanced clinical candidate. In addition, operating as a publicly-traded company may involve the hiring of additional financial and other personnel, upgrading financial information systems, and incurring other costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

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, including raising additional financing through our purchase agreement and financing with Lincoln Park Capital and other sourses. 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.

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 cytisine, as well as a granted patent in several European countries including Germany, France and Italy related to new oral dosage forms of cytisine 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, we have paid Sopharma $10 pursuant to the Sopharma License Agreement.

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, we will exclusively purchase all of our cytisine from Sopharma, Sopharma agrees to exclusively supply all such cytisine requested by us, for territories as detailed in the licensing agreement, and we extended the term to 2037. In addition, Achieve will have full access to the cytisine supply chain and Sopharma will manufacture sufficient cytisine to meet a forecast for a specified demand of cytisine 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 cytisine and its derivatives, including a number of patent applications related to novel approaches to cytisine 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 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 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.

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 cytisine to the University of Bristol as an initial contribution. To date, we have not paid any further sums to the University of Bristol pursuant to the University of Bristol License Agreement.

Product Candidate Cytisine

Our product candidate, cytisine, is a naturally occurring plant-based alkyloid from the seeds of the *Laburnum anagyroides* plant. Cytisine is a smoking cessation aid believed to interact with nicotine receptors in the brain, reducing the severity of nicotine withdrawal symptoms and the reward and satisfaction associated with smoking.

Cytisine is an established 25 day smoking cessation treatment that has been approved and marketed in Central and Eastern Europe by a third party for over 20 years under the brand name TabexTM. As of December 2016, it is estimated that over 21 million people have used cytisine to help combat 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.

Product Candidate Apatorsen

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, notifying them that we have discontinued development of apatorsen resulting in termination of the license agreement related to this product candidate. We intend to also terminate the University of British Columbia, or UBC, license agreement related to apatorsen provided that Ionis does not exercise its reversion rights within 90 days of the notice of discontinuance. If Ionis exercises its reversion rights related to apatorsen, we believe Ionis will assume the rights and obligations under the UBC license agreement. 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.

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 the number of projects and 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 cytisine. (See “Item 1A. Risk Factors—Risks Related to the Development of Our Product Candidates.”)

Successful development of cytisine 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, 2017:

	Total Outstanding and Exercisable	Exercise price per Share	Expiration Date
(1) Series A Warrants issued in July 2014 financing	252,721	44.000	July 2019
(2) Series B Warrants issued in July 2014 financing	60,933	44.000	July 2019

No warrants were exercised during the nine months ended September 30, 2017 or 2016.

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 shares of our common stock for a period that coincides with the expected life of the warrants.

Results of Operations

For the three and nine months ended September 30, 2017 and 2016

Research and development expenses

Our research and development expenses for our clinical development program for the three and nine months ended September 30, 2017 and 2016 are as follows (in thousands):

	Three months ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Clinical development programs:				
Cytisine	$ 203	$ 69	$ 326	$ 206
Other research and development	$ 622	$ —	$ 622	$ —
Total research and development expenses	**$ 825**	**$ 69**	**$ 948**	**$ 206**

Research and development expenses for the three and nine months ended September 30, 2017 increased to $0.8 million and $0.9 million, respectively, from $0.1 million and $0.2 million for the three and nine months ended September 30, 2016, respectively. The increase in 2017 as compared to 2016 was due to increased employee expenses and higher facilities costs resulting from the reverse merger of OncoGenex and increased research and development activity for our cytisine clinical development program, including the costs associated with filing the IND application and initiating the food effects trial.

General and administrative expenses

General and administrative expenses for the three and nine months ended September 30, 2017 increased to $1.6 million and $1.9 million, respectively, from $0.3 million and $0.9 million for the three and nine months ended September 30, 2016, respectively. The increase in 2017 as compared to 2016 was due to increase 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.

Gain / (loss) on warrants

We recorded a gain of $0.1 million and $0.1 million on the revaluation of our outstanding warrants for the three and nine months ended September 30, 2017, respectively.

Bargain purchase gain

In accordance with ASC 805, “Business Combinations,” the excess of fair value of acquired net assets over purchase price (negative goodwill) of $1.3 million, was 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. (See Note 2 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q)

Contingent value rights recovery

The contingent value rights issued by Oncogenex to its shareholders prior to the closing of the Arrangement, 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 apatorsen. A recovery of $0.2 million was recognized on our Consolidated Statements of Loss and Comprehensive Loss. (See Note 2 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q)

Loss on disposition of intangible asset and Recovery of deferred income taxes

In August 2017, we discontinued further development of apatorsen. 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. (See Note 4 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q)

Liquidity and Capital Resources

We have incurred an accumulated deficit of $8.9 million through September 30, 2017, 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.

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 from alternative sources. 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 (See Note 2 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q) and equity financing (See Note 8 to the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q). Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

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, including raising additional financing through our purchase agreement and financing with Lincoln Park Capital and other sources. 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.

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.

Pursuant to the Purchase Agreement, LPC initially purchased 328,947 of our units, or the Units, purchase price of $3.04 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 $3.496 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 80,000 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 $2.00 per share. As consideration for entering into the Purchase Agreement, we issued to LPC 123,516 shares of common stock; no cash proceeds were received from the issuance of these shares.

From September 14, 2017 through November 9, 2017, we offered and sold 873,778 shares of our common stock pursuant to our Purchase Agreement with LPC, including the 328,947 shares that were part of the initial purchase of Units. These sales resulted in gross proceeds to us of approximately $2.1 million and offering expenses of $0.1 million. As of November 9, 2017 shares of our common stock having an aggregate value of approximately $8.9 million remained available for sale under this offering program.

Cash Flows

Cash Used by Operations

For the nine months ended September 30, 2017, net cash used in operating activities was $5.5 million compared to $0.1 million for the nine months ended September 30, 2016. The increase in cash used in operations in 2017 as compared to 2016 was primarily attributable to increased personnel and facilities assumed in the Arrangement, increased research and development expenses for our cytisine development program and cash used to reduce liabilities assumed in the Arrangement.

Cash Provided by Financing Activities

For the nine months ended September 30, 2017, net cash provided in financing activities was $1.1 million compared to net cash provided by financing activities of $0.1 million for the nine months ended September 30, 2016. Net cash provided by financing activities in the nine months ended September 30, 2017 relates to proceeds received from our purchase agreement with LPC. Net cash provided by financing activities in the nine months ended September 30, 2016 relates to proceeds from promissory notes payable to a certain shareholder.

Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2017 was $12.4 million compared to zero for the nine months ended September 30, 2016. Net cash provided by investing activities in the nine months ended September 30, 2017 was due to the reverse merger of OncoGenex. There were no investing activities for the nine months ended September 30, 2016.

Operating Capital and Capital Expenditure Requirements

As of September 30, 2017, we had cash and cash equivalents of $8.0 million and a positive working capital balance of $6.3 million. 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, including raising additional financing through our purchase agreement and financing with Lincoln Park Capital and other sources. 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. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its research and development activities or other operations and potentially delay product development in an effort to provide sufficient funds to continue its operations. If any of these events occurs, the Company's ability to achieve its development and commercialization goals would be adversely affected.

Our future capital requirements will depend on many factors, including:

- the initiation, timing and cost of our clinical trials for cytisine;
- the scope and results of our clinical trials;
- the number of regulatory programs we pursue;
- the terms and timing of any strategic alliance, licensing and other arrangements that we may establish;
- our ability to forecast the cost of our ongoing development activities;
- whether we experience delays in our development program of cytisine, or experience slower-than-anticipated product development or rate of events;
- conducting studies required to obtain regulatory approvals for cytisine from regulatory agencies;

- the availability of third parties to perform the key development tasks for cytisine, including conducting preclinical studies and clinical trials and manufacturing cytisine to be tested in those studies and trials and the associated costs of those services;
- the costs involved in preparing, filing, prosecuting, maintaining, defending the validity of and enforcing patent claims and other costs related to patent rights and other intellectual property rights, including litigation costs and the results of such litigation;
- whether opportunities to acquire additional product candidates arise and the costs of acquiring and developing those product candidates;
- the costs to defend, and the results of, litigation;
- the cost and timing of hiring new employees to support our continued growth; and
- whether we engage in commercialization and product launch activities.

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

Off-Balance Sheet Arrangements

We did not have any off-balance sheet financing arrangements at September 30, 2017.

Commitments and Contingencies

We previously disclosed certain contractual obligations and contingencies and commitments relevant to us within the financial statements in our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC, on June 6, 2017. There have been no material changes to our “Commitments and Contingencies” note disclosure in our audited financial statements for the year ended December 31, 2016 in our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC, on June 6, 2017.

Material Changes in Financial Condition

(in thousands)	September 30, 2017	December 31, 2016
Total Assets	$ 13,029	$ 3,807
Total Liabilities	2,347	3,197
Total Equity	10,682	610

The increase in assets at September 30, 2017 compared to December 31, 2016 primarily relates to increase in cash and cash equivalents following the Arrangement. The decrease in liabilities at September 30, 2017 compared to December 31, 2016 was primarily due to lower stockholder loans with related parties and lower accrued compensation.

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, 2016 in our Amendment No. 3 to the Registration Statement on Form S-4/A filed with the SEC, on June 6, 2017. 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 2017, none of which had a material impact on our financial statements, and the future adoption of recently issued accounting standards, which we do not expect to have a material impact on our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Interest rate risk is the risk that the fair values and future cash flows of financial instruments will fluctuate because of the changes in market interest rates. We invest our cash in a variety of financial instruments, primarily in short-term bank deposits, money market funds, and domestic and foreign commercial paper and government securities. These investments are denominated in U.S. dollars, and we monitor our exposure to interest rate changes. We have very limited interest rate risk due to having only a few assets or liabilities subject to fluctuations in interest rates. Our investment portfolio includes only marketable securities with active secondary or resale markets to help ensure portfolio liquidity. Due to the nature of our highly liquid marketable securities, a change in interest rates would not materially change the fair market value. We have estimated the effect on our portfolio of a hypothetical increase in interest rates by 1% to be a reduction of approximately $50,000 in the fair value of our investments as of September 30, 2017.

Foreign Currency Exchange Risk

We are exposed to risks associated with foreign currency transactions on certain contracts and payroll expenses related to our Canadian subsidiary, Achieve Life Sciences Technologies, Inc., denominated in Canadian dollars, and we have not hedged these amounts. As our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. Accordingly, changes in the value of the U.S. dollar relative to the Canadian dollar might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period. We have estimated the effect on our reported results of operations of a hypothetical increase of 10% in the exchange rate of the Canadian dollar against the U.S. dollar to be approximately $0.1 million for the three months ended September 30, 2017.

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, 2017, 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, 2017 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 cytisine, 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 cytisine;
- advance cytisine development into larger, more expensive clinical trials;
- initiate additional pre-clinical, clinical, or other trials or studies for cytisine;
- seek to attract and retain skilled personnel;
- undertake the manufacturing of cytisine or increase volumes manufactured by third parties;
- seek regulatory and marketing approvals and reimbursement for cytisine;
- 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 cytisine 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.

Our ability to continue as a going concern is 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 candidates.

We have expended and continue to expend substantial funds in connection with our product development activities and clinical trials and regulatory approvals. Funds generated from our operations will be insufficient to enable us to bring all of our products currently under development to commercialization. Accordingly, we need to raise additional funds from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of our product candidates. 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, testing, production and marketing for some of our product candidates. 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 candidates;
- 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. If we cannot, we may need to delay, reduce or eliminate some or all of our research and development programs, any of which would be expected to have a material adverse effect on our business, operating results, and financial condition.

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 cytisine. 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 cytisine;
- obtaining regulatory and marketing approvals for cytisine;
- 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 cytisine, 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 cytisine that supports profitability;
- gaining market acceptance of cytisine as a treatment option;
- addressing any competing products including the potential for generic cytisine 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 candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets

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

Our single product candidate, cytisine, 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 cytisine 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 cytisine, which we may not be able to do on commercially viable terms or at all.

If we are unable to successfully commercialize cytisine due to failure to obtain regulatory approval or due to other risk factors outlined herein, our business, financial condition, and results of operations will be materially harmed as cytisine is currently our sole product candidate.

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.

Our principal stockholders own a significant percentage of our stock and will be able to exert significant control over us on matters subject to stockholder approval.

Our principal stockholders and their affiliates currently beneficially own approximately 57.3% of our outstanding voting stock. Therefore, these stockholders have the ability, and may continue to have the ability, to influence us through this ownership position. These stockholders are able to determine some or all matters involving us that require stockholder approval. For example, these stockholders, acting together, are able to control elections of directors, amendments of organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This control may prevent or discourage unsolicited acquisition proposals or offers for our common stock.

Risks Related to the Development of Our Product Candidates

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

We are currently dependent on the potential development of a single product candidate, cytisine. We are still developing our sole product candidate, and cytisine 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 cytisine for sale and marketing, and even if cytisine 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 cytisine in one or more markets, there is no assurance that we will be able to successfully market cytisine or that cytisine will achieve market acceptance sufficient to generate profits. Failure to develop cytisine, to obtain regulatory approval for cytisine, to successfully market cytisine, or to generate profits from the sale of cytisine would have material adverse effects on our business, financial condition, and results of operations.

Results of earlier clinical trials of cytisine are not necessarily predictive of future results, and any advances of cytisine 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 cytisine. Positive results in pre-clinical testing and past clinical trials with respect to the safety and efficacy of cytisine 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 cytisine, 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:

- 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;
- 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;
- 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 cytisine;

- 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 cytisine; and
- delays in the time for manufacture of sufficient quantities of cytisine for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for cytisine could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to cytisine, 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 cytisine and may harm our business and results of operations.

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

- regulatory authorities may withdraw approvals of cytisine;
- regulatory authorities may require additional warnings on the cytisine 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 cytisine, 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 cytisine or our other product candidates may experience. The number of subjects exposed to cytisine 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 cytisine will be uncovered. Such rare and severe side effects may only be uncovered with a significantly larger number of patients exposed to cytisine. If such safety problems occur or are identified after cytisine reaches the market in the United States, or if such safety problems occur or are identified in foreign markets where cytisine is currently marketed, the FDA may require that we amend the labeling of cytisine or recall it, or may even withdraw approval for cytisine.

If the use or misuse of cytisine harms patients, or is perceived to harm patients even when such harm is unrelated to cytisine, 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 cytisine in clinical trials and the sale of cytisine 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 cytisine 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 cytisine. 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 cytisine, if any, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to cytisine, 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 cytisine 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 cytisine, 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 cytisine 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, cytisine;
- 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 cytisine 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, cytisine, is derived from the seeds of the *Laburnum anagyroides* plant, which grows in the mountains of Southern Europe. We currently secure cytisine 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 cytisine. Sopharma currently has planted approximately 600,000 laburnum trees, saplings and seedlings in multiple locations in Central and Eastern Bulgaria. 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 cytisine. In the event we are no longer able to obtain cytisine 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 cytisine from the *Laburnum anagyroides* plant depends on the availability of natural resources, including sufficient rainfall. Our exclusive supplier of cytisine, 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 cytisine 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 cytisine 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 cytisine by the FDA, or the commercialization of cytisine, 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 Cytisine 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 cytisine.

We will need approval from the FDA, to commercialize cytisine in the United States and approvals from similar regulatory authorities in foreign jurisdictions to commercialize cytisine in those jurisdictions. In order to obtain FDA approval of cytisine, we must submit an NDA to the FDA, demonstrating that cytisine 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 cytisine 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 cytisine. 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. While we intend to begin a pivotal Phase 3 trial in the first half of 2018, the FDA may require us to conduct additional Phase 3 trials, including if it deems the earlier trials involving cytisine to be insufficient or not available to support a single additional Phase 3 trial. 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 cytisine. Failure to obtain approval from the FDA or comparable regulatory authorities in foreign jurisdictions to commercialize cytisine 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 cytisine for sale either within or outside the United States.

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

Even if cytisine 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 cytisine, if any, may be subject to limitations on the approved indicated uses for which cytisine 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 cytisine. 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 cytisine 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 cytisine 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 Achieve expects 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 cytisine, 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 cytisine, 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 cou ld 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 cytisine 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 cytisine, primarily in the United States, the European Union (including the United Kingdom) and Japan. Because we devote substantially all of our resources to the development of cytisine and rely on cytisine 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 cytisine 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 cytisine for use in clinical trials, and we intend to exclusively rely on Sopharma to produce and process cytisine, if approved. Our commercialization of cytisine 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 cytisine on a clinical or commercial scale. We currently exclusively rely on Sopharma to manufacture cytisine for use in clinical trials and plan to continue relying on Sopharma to manufacture cytisine on a commercial scale, if approved.

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

- Sopharma might be unable to timely manufacture cytisine 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 cytisine;
- we do not own the intellectual property rights to cytisine, and Sopharma could license such rights to third parties or begin supplying other third parties with cytisine; and
- Sopharma could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of cytisine by the FDA or the commercialization of cytisine 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 cytisine 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 cytisine 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 candidates 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 cytisine in the event that cytisine 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 cytisine 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 cytisine may be delayed or terminated and we may not be able to meet our current plans with respect to cytisine. 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 cytisine.

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 cytisine. 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 cytisine.

We may enter into a collaboration with third parties concerning the development and/or commercialization of cytisine; 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 cytisine;
- 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 cytisine, 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 cytisine if the collaborators view cytisine 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 cytisine, 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 cytisine.

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

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 appli cable 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 Cytisine

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 cytisine 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, Invion, Embera Neurotherapeutics, Redwood Scientific Technologies, Inc., 22nd Century Group, Inc., Quit4Good, Chrono Therapeutics, NAL Pharmaceuticals, Selecta Biosciences, Aradigm 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 cytisine. 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 cytisine 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 cytisine 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 cytisine and decrease our ability to generate revenue.

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

- the efficacy, if any, of cytisine 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 cytisine'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 cytisine;
- the publicity concerning cytisine 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 cytisine.

Even if cytisine displays a favorable efficacy and safety profile upon approval, market acceptance of cytisine remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of cytisine, 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 cytisine, 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 cytisine, 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 cytisine, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of cytisine 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 cytisine for free or we may not be able to successfully commercialize cytisine.

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 cytisine and what reimbursement codes cytisine 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 cytisine, if any, may be more difficult to achieve even if regulatory approval is received.

Sopharma may breach its supply agreement with us and sell cytisine into our territories or permit third parties to export cytisine 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 cytisine directly into our territories or permit third parties to export cytisine 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 cytisine, stolen products, or alternative third party distribution and sale of cytisine could have a negative impact on our financial performance or reputation.

Cytisine 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 cytisine 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. Other than regulatory exclusivity or other limitations, there may be little to nothing to stop these third parties from manufacturing, selling or distributing cytisine. Because we have no ability to set rigorous safety standards or control processes over third party manufacturers, sellers or distributors of cytisine, excluding Sopharma, these formulations of cytisine may be unsafe or cause adverse effects to patients and negatively impact the reputation of cytisine as a safe and effective smoking cessation aid.

Third parties could illegally distribute and sell counterfeit versions of cytisine, 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 cytisine products could materially affect patient confidence in our cytisine product. It is possible that adverse events caused by unsafe counterfeit or other non-Achieve cytisine products will mistakenly be attributed to our cytisine 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 cytisine 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 cytisine brand, Tabex, is currently approved for sale in certain Central and Eastern European countries. Cytisine 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 cytisine 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 European Union. 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 cytisine, 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 cytisine on terms that are acceptable to us, or at all. This may be because cytisine 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 cytisine's patent protection insufficient, and/or third parties may not view cytisine 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 cytisine could delay the development or commercialization of cytisine, 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 candidates or bring them 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 cytisine, 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 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 product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, 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 cytisine, 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 candidates 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 candidates 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 cytisine 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 cytisine 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 cytisine. 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 product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

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. Cytisine is a naturally-occurring product and is not patentable. Our intellectual property strategy involves novel formulations of cytisine and there is no guarantee that such patents will be issued or if issued, will be broad enough to prevent competitors from developing competing cytisine products. Although we do not believe that any patents that may issue from our pending patent applications directed at our product candidates, if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

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

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

Risks Related to our Common Stock

The price for our common stock is volatile.

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

- The ability of us or our partners to develop cytisine and other product candidates and conduct clinical trials that demonstrate such product candidates are safe and effective;
- our ability or our partners to obtain regulatory approvals for cytisine 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 opinions 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 the 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.

If the ownership of our common stock is highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Executive officers and directors and their affiliates beneficially own or control a significant percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit the other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise

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 80,000 shares of common stock, with such amounts increasing as the closing sale price of our common stock increases. The purchase price of shares of common stock pursuant to the Purchase Agreement have been and will be based on prevailing market prices of common stock at the time of sale without any fixed discount, and we have controlled and will control the timing and amount of any sales of common stock to LPC. In addition, we have directed and we may direct LPC in the future to purchase additional amounts as accelerated purchases if on the date of a regular purchase the closing sale price of the common stock is not below $2.00 per share. 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.

Item 6. Exhibits

Exhibit Number	Description
2.1	Amendment No. 2 to Agreement and Plan of Merger and Reorganization, dated July 19, 2017, by and among Achieve Life Sciences, Inc., Ash Acquisition Sub, Inc., Ash Acquisition Sub 2, Inc., and Achieve Life Science, Inc. (Incorporated by referenced to Exhibit 10.1 to the Current Report on Form 8-K filed on July 19, 2017)
10.1*	Amended and Restated Supply Agreement, dated July 28, 2017, by and between Achieve Life Science, Inc., and Sopharma AD
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Portions of this exhibit have been omitted based on an application for confidential treatment submitted to the SEC. The omitted portions of this exhibit have been filed separately with the SEC.

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 9, 2017

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

Date: November 9, 2017

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

EXHIBIT 10.1

[***] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

AMENDED AND RESTATED COMMERCIAL AGREEMENT ON SUPPLY OF PHARMACEUTICAL PRODUCTS

This **Amended and Restated Commercial Agreement** ("**Supply Agreement**" or "**Agreement**") is made as of July 28, 2017 (the "**Effective Date**") by and between Achieve Life Science, Inc., a Delaware corporation having a registered address at 1209 Orange Street, Wilmington, Delaware 19801 ("**Achieve**") and Sopharma AD, having a registered address at 16 Iliensko Shose Boulevard, 1220 Sofia, Bulgaria ("**Sopharma** "). Achieve and Sopharma may be referred to herein individually as a "**Party,** " and collectively as the "**Parties**."

BACKGROUND

A. Sopharma owns certain patent rights and controls certain proprietary technology relating to the manufacture of Cytisine and pharmaceutical compositions containing Cytisine, and Sopharma exclusively licensed such patent rights and technology to Extab Corporation (a wholly owned subsidiary of Achieve) ("**Extab**") in the Territory under that certain Exclusive License Agreement dated May 26, 2009, as amended May 14, 2015 (the "**License Agreement**").

B. Sopharma and Extab entered into a Commercial Agreement on Supply of Pharmaceutical Products dated February 1, 2010, as amended May 14, 2015 (the "**Commercial Agreement**"), whereby Extab agreed to purchase Cytisine products from Sopharma.

B. The Parties now wish to restate and amend the Commercial Agreement such that Achieve agrees to exclusively purchase from Sopharma, and Sopharma agrees to exclusively supply to Achieve, all of Achieve's requirements for Products for the Territory upon the terms conditions set forth herein.

NOW, **THEREFORE**, in consideration of the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

AGREEMENT

ARTICLE 1
DEFINITIONS / INTERPRETATION

For the purposes of this Supply Agreement, the following capitalized words and phrases shall have the following meanings:

1.1 "**Active Agent**" means the active pharmaceutical ingredient (-)-Cytisine, as derived from plant genera, including but not limited to *Laburnum* and *Cytisus* of the family Fabaceae, and any intermediates, salts and esters thereof.

1.2 "**Affiliate**" means, with respect to either Party, any business entity controlling, controlled by, or under common control with such Party. For the purpose of this definition only, "control" means (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a business entity.

1.3 "**Applicable Law**" means all laws, ordinances, rules, rulings, directives and regulations of any Governmental Authority that apply to the development, Manufacture or supply of the Products in the Territory, or any other activities contemplated under this Supply Agreement, including any regulations and guidelines of the FDA, EMA and other Regulatory Authorities.

1.4 "**Bulk API**" means the Active Agent in bulk form.

1.5 "**cGMPs**" means then current good manufacturing practices and standards for the manufacture of pharmaceutical products under Applicable Law in the Territory or the country in which the Products are Manufactured.

1.6 "**Commercially Reasonable Efforts**" means the carrying out of obligations or tasks in a diligent, sustained manner consistent with the reasonable best practices of the pharmaceutical industry for the manufacture, supply and distribution, as applicable, of a product having similar manufacturing complexity and specifications and of similar profit potential and strategic value, in each case based on conditions then prevailing. Commercially Reasonable Efforts requires that the Party: (a) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.7 **"Contingency Product"** means 200 kilograms of Product to be stockpiled.

1.8 "**EMA**" means the European Medicines Agency or any other successor agency whose approval is necessary to commercialize the Product in Europe.

1.9 "**Ex Works**" means the term Ex Works as defined in the ICC Incoterms, 2010.

1.10 "**Facility" or "Facilities**" means the facilities where Product will be Manufactured as set forth in Exhibit 1. Exhibit 1 may be amended from time to time in accordance with this Supply Agreement to add or remove Facilities.

1.11 "**FDA**" means the United States Food and Drug Administration, or any successor agency whose approval is necessary to commercialize the Product in the United States.

1.12 "**Finished Product(s)**" means the Active Agent, as formulated in finished form and packaged according to the Specifications.

1.13 **"Forecast "** means the quantities of each Product estimated to be required during one calendar year.

1.14 "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any nation, state, country, city or other political subdivision, including any Regulatory Authority.

1.15 "**Manufacture**" or "**Manufacturing**" means the processes and procedures for the supply of the Products, including, (b) the manufacture of the Products in bulk; (c) the Packaging and labeling of the Products; (d) the quality control of the Products; and (e) the storage of the Products until shipment.

1.16 "**Net Sales**" means the gross receipts ("**Gross Sales**") representing sales of Product to Third Parties in Finished Product form, by Achieve, its Affiliates, or sublicensees and their Affiliates in the Achieve Territory throughout the term of this Agreement , less deductions actually allowed or specifically allocated to the Product for:

a) Transportation charges, including, without limitation, insurance for transporting the Product to the extent that such charges are billed to the purchaser by Achieve or its Affiliates;

b) Sales, excise and consumption taxes and custom duties, and any other governmental charges imposed on the production, importation, use or sale of the Product, to the extent that such charges are billed to the purchaser by Achieve or its Affiliates;

c) Trade, quantity, cash or other discounts allowed on the Product not already reflected in the amount invoiced;

d) Allowances or credits to customers for rejection or return of the Product;

e) Retroactive price reductions affecting the Product; and

f) Rebates, credits, charge backs, fees, reimbursements or similar payments that are granted to wholesalers or other distributors, government entities, managed care entities or other customers.

Each of the foregoing deductions from Gross sales shall be deducted only once and only to the extent not otherwise deducted from Gross sales. Any sale of Product between Achieve and its Affiliates, including all samples, will be excluded from the computation of Net Sales. If Achieve or its Affiliates sell the Finished Product as part of a bundle with other products, and Achieve or its Affiliates provide a discount, allowance or rebate to the purchaser of such products based on the invoiced prices for all products sold, such discount must be allocated pro-rata to the Product based on the selling prices of all products sold in the bundle before taking into account the discount, allowance or rebate on Product provided as part of such bundle.

If the Finished Product is sold or otherwise commercially exploited by Achieve or its Affiliates in a manner that makes calculating Net Sales impossible or inappropriate, the Parties agree to negotiate in good faith a reasonable mechanism for calculating said Net Sales. Net Sales shall be determined in accordance with International Financial Reporting Standards (IFRS).

For the avoidance of doubt any disposal of Finished Product for, or use in, clinical trials or as free samples (such samples to be in quantities common in the pharmaceutical industry for similar products) shall not give rise to any sale for the purpose of calculating Net Sales.

1.17 "**Package**" or "**Packaging**" means packaging Product(s) in accordance with applicable Specifications.

1.18 "**Person**" means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency thereof.

1.19 "**Price**" means the price paid by Achieve for each Product as set forth on Exhibit 1 of this Supply Agreement and as may be modified from time to time in accordance with Section 3.2.

1.20 "**Product(s)**" means Bulk API and/or Finished Product, as applicable.

1.21 "**Regulatory Approval**" means, with respect to a Product, all approvals, licenses, registrations or authorizations necessary to market and sell such Product in a particular jurisdiction in the Territory (including applicable approvals of labeling, price and reimbursement for such Product in such jurisdiction).

1.22 "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity (including the FDA and EMA) with authority over the development, Manufacture or commercialization (including approval of Regulatory Approvals) of any Product in any jurisdiction in the Territory.

1.23 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority (including minutes of meeting with Regulatory Authorities) related to the development, Manufacture, marketing, sale or other commercialization of any Product in any regulatory jurisdiction in the Territory.

1.24 "**Sopharma Know-How**" means the Licensed Technical Information and Licensed Technology, as defined in the License Agreement.

1.25 "**Sopharma Territory**" means Albania, Algeria, Armenia, Austria, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Finland, Georgia, Hungary, Kazakhstan, Kosovo, Kyrgyzstan, Latvia, Lithuania, Libya, Macedonia, Moldova, Mongolia, Norway, Poland, Romania, Russia, Serbia, Slovakia, Sweden, Tajikistan, Tunisia, Turkey, Turkmenistan, Ukraine, Uzbekistan, Vietnam, Iran and Afghanistan.

1.26 "**Specifications**" means, with respect to a Product, all product, regulatory, Manufacturing, release criterion, quality control and quality assurance procedures, processes, practices, standards, instructions and specifications applicable to the Manufacture of such Product, as set forth in the Regulatory Approval for the Product and the Technical and Quality Agreement.

1.27 "**Technical and Quality Agreement**" means the agreement between the Parties dated May 14, 2015, as may be amended from time to time in writing by the Parties, which agreement sets forth the specific responsibilities, procedures and guidelines for batch release, quality control testing, quality assurance review, acceptance testing and other quality-related aspects of the manufacture and release of Product hereunder.

1.28 "**Territory**" means all countries, territories and regions of the world, excluding the Sopharma Territory.

1.29 "**Third Party**" means any Person other than Achieve, Sopharma or their respective Affiliates.

ARTICLE 2
SUPPLY

2.1 **Supply**.

2.1.1 **Sopharma**.

(a) Pursuant to the terms and conditions herein, Sopharma shall Manufacture the Products at the Facility for Achieve and shall supply all of Achieve's requirements of the Products necessary or required for Achieve's development, use and sale in the Territory.

(b) Sopharma agrees and covenants that it will supply the Products exclusively to Achieve in the Territory, and will not Manufacture or supply the Products in the Territory for its own, its Affiliates or any Third Party's development, use or sale in the Territory.

(c) During the term of this Agreement, Sopharma shall not sell, transfer or otherwise provide, directly or indirectly, to any Third Party any Product for use or sale in the Territory. To the extent not prohibited by applicable law, Sopharma shall restrict (through contracts and/or purchase orders, marketing literature, shipping documents, or similar documents used when a supply, distribution or similar agreement is not in place) its customers and distributors and require similar restrictions throughout the supply chain, from selling or providing any Product for use or sale in the Territory. Sopharma shall use its best efforts to enforce such restrictions, including without limitation by (i) notifying such customer or distributor in writing of such alleged violation, (ii) conducting an investigation of such alleged violation reasonably appropriate under the circumstances, and (iii) if the investigation confirms the violation, Sopharma shall address a written warning to such customer or distributor for stopping the selling or providing the Product for use or sale in the Territory and (iv) suspending shipments of Product to a customer or distributor if Sopharma becomes aware that such customer or distributor is selling or providing such Product for use or sale in the Territory if it does not cease the violation within three (3) months as of the receiving of the written warning.

2.1.2 Achieve.

(a) Subject to the terms and conditions herein, Achieve shall purchase all of its requirements of Products necessary or required for Achieve's development, use and sale in the Territory exclusively from Sopharma. For clarity, during the term of this Supply Agreement, Achieve may in its discretion elect to purchase from Sopharma Bulk API (and manufacture finished product, whether on its own or through Third Parties) and/or Finished Product.

(b) During the term of this Agreement, Achieve shall not sell, transfer or otherwise provide, directly or indirectly, to any Third Party any Product for use or sale in the Sopharma Territory. To the extent not prohibited by applicable law, Achieve shall restrict (through contracts and/or purchase orders, marketing literature, shipping documents, or similar documents used when a supply, distribution or similar agreement is not in place) its customers and distributors and require similar restrictions throughout the supply chain, from selling or providing any Product for use or sale in the Sopharma Territory. Achieve shall use its best efforts to enforce such restrictions, including without limitation by (i) notifying such customer or distributor in writing of such alleged violation, (ii) conducting an investigation of such alleged violation reasonably appropriate under the circumstances, and (iii) if the investigation confirms the violation, Achieve shall address a written warning to such customer or distributor for stopping the selling or providing the Product for use or sale in the Sopharma Territory and (iv) suspending shipments of Product to a customer or distributor if Achieve becomes aware that such customer or distributor is selling or providing such Product for use or sale in the Sopharma Territory if it does not cease the violation within three (3) months as of the receiving of the written warning.

(c) Achieve agrees and covenants that it will seek Regulatory Approval for and will commercialize the Products only in the Territory.

2.2 Forecasts.

2.2.1 Within three (3) months of signing of the present Agreement, Achieve shall provide Sopharma with a non-binding multi-year supply forecast (Multi-year forecast) of the quantities of each Product estimated to be required by Achieve and its Affiliates for the Territory during the 5 (five) year period beginning three (3) months from the Effective Date. Thereafter, during the Term, at least thirty (30) days prior to December 31 of each calendar year, Achieve shall provide Sopharma with a current forecast of the quantities of each Product estimated to be required during the following calendar year (such forecast for the next calendar year, the "**Forecast**"). Achieve shall update the Forecast every six (6) month period thereafter. The Forecast and the Forecast updates shall not reduce or increase the estimated quantities of more than 10% of the Multi-year forecast for the respective period. The forecasted quantities for each Forecast and any update thereto increased or reduced up to 30% shall not be binding on the Parties. Sopharma shall notify Achieve as soon as possible, but in any event within thirty (30) days of receipt of a Forecast or update thereto, if Sopharma believes it will be unable to deliver Product in accordance with such Forecast or update thereto, and such notice will be deemed as Shortfall Notice as defined in Section 2.8.1(a).

2.2.2 **Purchasing obligation**. Notwithstanding anything to the contrary herein, Achieve agrees and covenants to purchase the forecasted quantities of each Product for each Forecast and any updates thereto throughout the term. In the event that Achieve is not in compliance with its purchasing obligations under this Supply Agreement, or is unable to comply with its obligations hereunder, then Sopharma shall be entitled to receive a payment equal to the Supply price of the non-purchased quantities of the Products for the respective period.

2.3 **Orders**.

2.3.1 Purchase Orders.

(a) Achieve shall place purchase orders specifying the quantity of Product, destination(s) and delivery date(s) at least sixteen (16) weeks before the specified delivery date(s), provided that the first (launch) order shall be placed at least twenty-four (24) weeks in advance of the specified delivery date. Sopharma shall confirm all purchase orders for Product submitted by Achieve in accordance with this Article 2 within five (5) business days from receipt of the order (order confirmation). Confirmed purchase orders may not be cancelled without the prior written agreement of both Parties except as set forth in Section 2.4. Unless otherwise directed by Achieve, Sopharma shall fill all purchase orders for Product in accordance with the requested due dates as set forth in further detail in Section 2.8.2. Delivery time shall be calculated from the date of order confirmation and delivery shall be delivery of the Products and accompanying documentation, as set forth in the Technical and Quality Agreement, at the specified location.

(b) For a Product, Achieve shall place orders in multiple quantities of the minimum order quantity for that Product as set forth in Exhibit 1. Any order for a Finished Product placed by Achieve shall be for a minimum of [***] packs per delivery.

2.3.2 No Conflicting Terms. The terms and conditions of this Supply Agreement shall be controlling over any conflicting terms and conditions stated in Achieve's purchase order or Sopharma's invoice, confirmation or other standardized document. Any purchase order, order acknowledgement, invoice, proposal or other document which conflicts with or adds to the terms and conditions of this Supply Agreement with respect to the Manufacture and supply of Product for the Territory is hereby rejected, unless the Parties mutually agree to the contrary in writing.

2.4 **Cancellation**. Notwithstanding anything herein to the contrary, Achieve may modify or cancel purchase orders for the Products provided that such modification or change is made further in advance of the originally requested delivery date than the required lead time, and that production has not commenced.

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2.5 Delivery and Risk of Loss. Sopharma shall deliver all Product Ex Works, except that Sopharma shall, at the request and cost of Achieve, deliver Bulk API Product to Achieve or Achieve's Finished Product manufacturer, in which case Sopharma shall arrange for transportation of said Bulk API and title and risk of loss and damage thereto shall remain with Sopharma until the Bulk API is delivered to Achieve or its designee in accordance with the purchase order.

2.6 Packaging. If the purchase order is for Packaged Product, Achieve shall provide the relevant blister and Packaging designs to Sopharma at least sixteen (16) weeks prior to the scheduled delivery date. If Achieve is late to do so, the delivery date for Product shall be delayed by as many days as Achieve is late to deliver the designs. Sopharma shall deliver the Product to Achieve in Packaged form that is in accordance with the Required Standards. All costs for designing the Packaging shall be fully paid by Achieve.

2.7 Conformance to Required Standards.

2.7.1 Conformance to Required Standards. Sopharma shall Manufacture the Products in accordance with the Applicable Law and Specifications, as the same may be amended or supplemented from time to time. Each Party shall keep the other promptly and fully advised of any new instructions or Specifications required by any applicable Regulatory Authority or Applicable Law of which it becomes aware. The Parties shall confer with respect to the best mode of compliance with such requirements, and Sopharma shall promptly implement such reasonable requirements as requested by Achieve.

2.7.2 Technical and Quality Agreement. Each Party agrees to perform the responsibilities assigned to such Party under the Technical and Quality Agreement in accordance with the terms and conditions of the Technical and Quality Agreement, which forms an integral part of this Supply Agreement. In case of any conflict between the provisions of this Supply Agreement and those of the Technical and Quality Agreement, the Technical and Quality Agreement shall prevail as to any quality-related matter, and this Agreement shall prevail as to all other matters.

2.8 Supply and Delivery; Cooperation.

2.8.1 Shortfalls and Technology Transfer.

(a) In the event that Sopharma is unable or anticipates that it will be unable to supply Product in accordance with (i) the requirements of this Supply Agreement, including all Specifications and pursuant to Applicable Law, (ii) the then-current Forecast provided by Achieve, and/or (iii) the confirmed due dates as set forth in further in Section 2.3.1(a) (each, a "**Shortfall**"), Sopharma will promptly notify Achieve in writing ("**Shortfall Notice**").

(b) The Parties shall meet within ten (10) business days following Achieve's receipt of a Shortfall Notice. If the Parties agree on a plan to prevent or remedy such Shortfall ("**Remediation Plan**"), Sopharma shall promptly implement the Remediation Plan within the time period specified therein. Without limiting the foregoing, upon the earlier of (i)

receipt of a Shortfall Notice and (ii) Sopharma's failure to supply the applicable Product by the confirmed due dates as set forth in further in Section 2.3.1(a), then Achieve , in addition to any other rights or remedies available to it, shall have the right to take any measures available to it to mitigate its resulting losses during the period affected by such shortfall and for a period of twelve (12) months thereafter. Achieve shall also have the right to cancel orders for any quantities of Product affected by such Shortfall effective upon Achieve's receipt of the Shortfall Notice, and Achieve shall have no further obligations to purchase any such cancelled quantities of Product.

(c) In the event that Sopharma does not implement the Remediation Plan within the time period specified therein, or in the event a Shortfall lasts more than ninety (90) days, Achieve shall (i) be (to the extent so elected by Achieve in Achieve's discretion) relieved of the purchase obligations of any quantities of Product until such time as Sopharma has resumed the performance of its obligations to Achieve, subject to any minimum purchase obligations that may have been agreed upon by Achieve prior to such time for the expected period of Shortfall; (ii) be entitled to, in Achieve's discretion, supply the needed raw materials (plant genera flowers and seeds for deriving cytisine) to Sopharma, in which case Sopharma shall supply Product to Achieve as requested by Achieve on terms to be negotiated in good faith by the Parties for thirty (30) following Achieve's request (it being understood that if the Parties fail to agree to such terms with such thirty (30) day period, such terms shall be determined pursuant to Section 11.3.2) and (iii) Achieve and Sopharma will collaborate to deliver to a Third Party manufacturer the Sopharma Know-How and documentation required for such Third Party to extract the Active Agent and Manufacture Bulk API until such time as Sopharma has implemented the Remediation Plan and resumed the performance of its obligations to Achieve's reasonable satisfaction, it being understood that such Third Party may not use such Sopharma Know-How and/or documentation for any other purpose.

2.8.2 Delivery Delays . Sopharma shall deliver Product no more than twenty-one (21) days before or 30 (thirty) days after the delivery date specified in the relevant purchase order (the "**Delivery Time Period**"). For any failure to supply compliant Product in the Delivery Time Period, without limiting Achieve's other remedies, Sopharma shall be liable for any Third Party penalties, costs and expenses incurred by Achieve as a result of Sopharma's failure to supply compliant Product during the Delivery Time Period, subject to receipt by Sopharma of appropriate evidence of such penalties, costs and expenses. The rights of Achieve set forth in this paragraph are in addition to any other rights set forth in this Supply Agreement.

2.9 Other Shortfalls. If the quantities of Product set forth in the then-current Forecast pursuant to Section 2.2 are not sufficient to satisfy Achieve's requirements, Achieve may at any time notify Sopharma thereof, and Sopharma shall use Commercially Reasonable Efforts to supply the quantities of Product requested by Achieve in excess of those set forth in the Forecast, provided that Sopharma shall promptly confirm in writing whether or not it is willing to supply such quantities. In the event Sopharma (a) does not confirm within five (5) business days in writing that it is willing to supply such excess quantities by the delivery date(s) requested by Achieve, or (b) following a confirmation, fails to supply such excess quantities by the specified delivery dates requested by Achieve, then Achieve shall be free to purchase Product from any Third Party for such excess quantities.

2.10 Contingency Product. Achieve will purchase a total of 200 kilograms of Product as a contingency supply (Contingency Product) and make a deposit of $[***], to be credited as set forth below. The Contingency Product shall be used on a first-in/first out basis and the price shall be applied against the purchase price of the Active Agent Product or Finished Product when used or when the contingency supply is replenished. Such Contingency Product shall be stored in a segregated area with 50% held at the Kazanlak facility and 50% at the Sophia facility. A deposit of $[***] will be made on June 30, 2018 for [***] kilograms of Product and a further deposit of $[***] will be made on December 31, 2019 for [***] kilograms of Product. So long as a minimum of 200 kilograms of Product is maintained as a contingency supply on Achieve's behalf, Sopharma shall be entitled to retain the deposit amounts.

2.11 EU Launch. Upon Achieve's request, Sopharma shall provide reasonable assistance to Achieve in order to ensure an orderly transition of the tableting of the Product to a Third Party manufacturer in connection with the launch of the Product in Europe (outside of the Sopharma Territory).

2.12 Subcontracting by Sopharma. Sopharma may subcontract specific portions of its obligations hereunder to Third Parties in its reasonable discretion and upon advance notice to Achieve, and shall (a) ensure that any subcontractor of Sopharma's obligations under this Supply Agreement has and maintains all appropriate qualifications; (b) enter into a quality agreement with each such subcontractor which terms are similar to the terms of the Technical and Quality Agreement; (c) ensure that any subcontractor complies with cGMPs if applicable; and (d) be responsible for each subcontractor's performance hereunder (including performance or non-performance by such subcontractor that would constitute a breach of this Supply Agreement or such quality agreement if conducted by Sopharma) as if Sopharma were itself performing such activities.

ARTICLE 3
PRICING AND PAYMENT

3.1 Invoices. Sopharma shall invoice Achieve at the time of each shipment of Product for the Supply Price for such shipment. Achieve will pay such invoices within thirty (30) days of receipt of invoice by Achieve.

3.2 Prices.

3.2.1 The Supply Price for Bulk API and Finished Product to be supplied is set forth in Exhibit 1 hereto, subject to annual increase on April 1st of each year, based on the Producer Price Index for the European Union as published by the Organisation for Economic Co-Operation and Development (OECD) for the prior calendar year, such increase not to exceed [***]% but not less than [***]% in any one calendar year. For orders that do not meet the minimum order requirement for a Product, the Product will be invoiced at the Product's Supply Price plus [***]%.

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3.2.2 In the event the market price for a Product in a country in the Territory is less than the Supply Price for the Finished Product, the Parties shall negotiate in good faith a new Supply Price for the Finished Product or Bulk API for such country, taking into consideration changes in costs of raw materials, packaging, labor, overhead or other costs that are relevant to Manufacture of the Product. If the Parties agree on a new price, then that price will become the new Supply Price for that Product in that country. If the Parties are unable to agree on a new price within ten (10) days following Achieve's request, such price shall be determined pursuant to Section 11.3.2.

3.2.3 Achieve shall pay to Sopharma without set-off or counterclaim (save as otherwise permitted by this Agreement) a royalty of [***]% on Net Sales of Active Agent Product sold by Achieve, its Affiliates, or sublicensees and their Affiliates in the Achieve Territory throughout the Term on quarterly basis.

3.2.4 If Achieve fails to pay Sopharma invoices or royalties within their respective due dates, Sopharma shall be entitled to debit to Achieve, an interest equal to three months LIBOR plus 3 percentage points per annum, beginning with the first day after end of the above defined payment terms.

3.3 **Recordkeeping**. During the Term and for three (3) years thereafter, or for such longer period as may be required by Applicable Law, Sopharma shall prepare and retain, and shall cause its subcontractors to prepare and retain, accurate books and records related to transactions made pursuant to this Supply Agreement and the Prices. Such records shall be made available for reasonable review, audit and inspection upon reasonable notice and with reasonable frequency, upon Achieve's request for the purpose of verifying Sopharma's calculations of amounts due hereunder, the basis for such calculations or payments and Sopharma's compliance with the terms and conditions of this Supply Agreement. Audits and inspections may be conducted by Achieve's own personnel or retained consultant(s), subject to the confidentiality obligations set forth in this Supply Agreement.

3.4 **Taxes**. Sopharma agrees that all Prices shall be inclusive of, and that Sopharma shall bear all taxes, whether direct or indirect (including, by way of example, corporate income, sales and transfer taxes, and VAT), levies, and duties (including customs duties) as may be imposed on Sopharma (or for which Sopharma is required to act as withholding agent by any Governmental Authority on the subject matter of this Supply Agreement), and Sopharma shall be responsible for the timely payment of such amounts to such Governmental Authority.

ARTICLE 4
PRODUCT ACCEPTANCE

4.1 Sopharma shall provide the release documentation specified in the Technical and Quality Agreement with any batch of Product delivered to Achieve.

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4.2 Achieve shall review and inspect the (a) intactness of any Packaging, and (b) documentation provided by Sopharma pursuant to Section 4.1 for compliance with the Specifications. If the review and inspection conducted by Achieve indicates non-intact Packaging or non-conformance with any of the applicable Specifications, then Achieve shall inform Sopharma in writing that it is rejecting the Product within fourteen (14) days of receipt of delivery.

4.3 Any Product not rejected by Achieve as described in Section 4.2 shall be deemed accepted by Achieve except to the extent such Product contains a latent defect. Any Product containing a latent defect shall be deemed accepted by Achieve, unless such defect is identified and the Product is rejected by written notice to Sopharma prior to the end of the applicable shelf-life of the Product; provided, however, that Achieve shall notify Sopharma of any latent defect within fourteen (14) days the discovery of such defect by Achieve.

4.4 In the event Achieve notifies Sopharma of a defect pursuant to the foregoing Sections 4.2 and 4.3 and Achieve and Sopharma disagree over whether a batch of Product fails to comply with the Specifications, the Parties shall use their best efforts to resolve the disagreement first between themselves. In the event that the Parties are unable to negotiate a mutually agreeable resolution with ten (10) business days of notification by Achieve, the matter may be referred to a mutually agreed upon independent Third Party specializing in the analysis of similar products to determine whether the relevant batch conforms to the Specifications. The determination of such Third Party shall be deemed final and binding, and expenses incurred by such determination (including the expert's fees) shall be paid by the Party whose position is not supported by the Third Party's determination.

4.5 In the event that it is determined in accordance with Section 4.4 that a batch of Product does not meet the Specifications ("Defective Product"), then Achieve may, at is sole option: (i) either return the Defective Product to Sopharma or destroy the Defective Product, and request replacement of the Defective Product by Sopharma; or (ii) accept the Defective Product accompanied by a commensurate reduction of the invoice amount. With respect to Section 4.5(i), Sopharma shall pay for the return or destruction of any Defective Product, and shall use Commercially Reasonable Efforts to deliver to Achieve as promptly as possible the replacement quantities of conforming Product at Sopharma's sole expense, including payment for any necessary replacement materials, and including storage, packaging, shipping and insurance costs.

ARTICLE 5
INSPECTION

5.1 During the Term, Achieve or an Achieve Affiliate may, during normal working hours and upon reasonable advance written notice, inspect Sopharma's or its subcontractor's Facilities directly or indirectly involved in the performance of this Supply Agreement, provided that Achieve will schedule a formal quality inspection no more than two (2) times per year. During such an inspection the inspectors may inquire about the progress of the work being carried out by Sopharma or its subcontractor, and are in particular but not exclusively authorized to:

5.1.1 Inspect the Facilities and equipment used, or to be used, in the Manufacture of the Product(s);

5.1.2 Verify the qualifications of the employees and subcontractors carrying out such work and their use of the relevant equipment;

5.1.3 Evaluate all scientific techniques used by Sopharma, its subcontractors and their respective employees in the performance of this Supply Agreement and the procedures used in the creation and storage of samples of the Product(s);

5.1.4 Verify and evaluate information relating to the utilization of the Manufacturing capacity of Sopharma's Facilities or its subcontractor's Facilities;

5.1.5 Review correspondence, reports, filings and other documents from Regulatory Authorities to the extent related to the Manufacturing activities hereunder;

5.1.6 E valuate the implementation of all Manufacturing and process changes made with respect to the Product, including pursuant to any corrective action plan; and

5.1.7 Ascertain compliance with Applicable Laws, the Specifications and this Supply Agreement.

5.2 If after an inspection Achieve is not satisfied that Sopharma is complying with any of its obligations hereunder, then, without prejudice to any other rights available to it, Achieve shall notify Sopharma in writing of any changes or modifications reasonably required of Sopharma within thirty (30) days of such inspection, and Sopharma shall implement said changes or modifications as soon as possible and at its sole expense.

ARTICLE 6
REGULATORY AND QUALITY RESPONSIBILITIES

6.1 **Regulatory Responsibilities**. Sopharma shall obtain and maintain any and all regulatory and governmental permits, licenses and approvals that are necessary for Sopharma to Manufacture the Product(s) for Achieve or its Affiliates in accordance with the terms of this Supply Agreement and Applicable Law. As between the Parties, Achieve shall have the sole responsibility for all Regulatory Approvals of the Products in the Territory. Any reasonable expenses related to the Regulatory Approvals of the Products in the Territory shall be borne by Achieve.

6.2 **Regulatory Cooperation**. Sopharma agrees to promptly provide to Achieve as requested, and at no additional charge, all information and data in Sopharma's possession that is relevant, necessary or useful for Achieve and/or its Affiliates to apply for, obtain and maintain Regulatory Approvals for the Products in the Territory, including without limitation information relating to the Facility, or the process, methodology, raw materials and intermediates used in the Manufacture, processing or Packaging of the Products, including all information and data required to be submitted with or contained in any Regulatory Materials for any Regulatory Approval, or requested by or required to be provided to any Regulatory Authority, including the FDA and EMA. In addition, Sopharma agrees to reasonably cooperate with Achieve and/or its Affiliates with respect to its obligations to submit or report information relevant to the Products pursuant to Applicable Law.

6.2.1 Safety Data. Each Party understands and acknowledges that the other Party and its Affiliates may need to access and utilize and include certain Product safety data (*e.g.*, adverse event reports) generated or received by such Party and its Affiliates in its Regulatory Materials in its respective Territory as required by Applicable Law. Each Party shall have the right to share any and all such safety data generated by the other Party or the other Party's Affiliates with its Affiliates and Third Parties subject to Article 8.

6.3 Recalls. Each of Achieve and Sopharma will immediately inform the other in writing if it believes one or more batches of any Product will be subject to recall from distribution, withdrawal or some other field action, because a Product does not conform to the relevant Specifications, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of such Product. With respect to any Products in the Territory, Achieve shall have the final decision-making authority as to any such recall or field action and the sole right to initiate any such recall or field action, and Sopharma shall cooperate in the conduct of any recall or field action as reasonably requested by Achieve. In the event it is determined that such a recall resulted from a breach by either Party of any of its representations, warranties, duties or obligations under this Supply Agreement, such Party shall be responsible for the costs of the recall and shall reimburse the other Party as necessary; provided that if both Parties share responsibility with respect to such recall, the costs shall be shared in the ratio of the Parties' contributory responsibility.

6.4 Retention of Samples. Sopharma shall prepare and retain, and shall cause its subcontractors to prepare and retain, such samples and records with respect to the Products and their Manufacture as are required by Applicable Law (including, as applicable, cGMPs), the Specifications and/or Technical and Quality Agreement.

6.5 Regulatory Authority Inspections and Correspondence. Sopharma shall permit Regulatory Authorities to conduct inspections of any Facility at which any of the Manufacturing activities relating to the Products are performed, as such Regulatory Authorities may request, including pre-approval inspections, and shall cooperate with such Regulatory Authorities with respect to such inspections and any related matters. Sopharma shall give Achieve prior written notice of any such inspections, and shall keep Achieve informed about the results and conclusions of each such regulatory inspection, including actions taken by Sopharma to remedy conditions cited in such inspections. In addition, Sopharma shall allow Achieve or its representative to assist in the preparation for and be present at, and participate in, such inspections, subject to the confidentiality obligations set forth herein. Sopharma shall provide Achieve with copies of any written inspection reports issued by any Regulatory Authority and all correspondence between Sopharma and any Regulatory Authority with respect thereto, including any notices of observation and all related correspondence, in each case relating to the Products or their Manufacture or to general manufacturing concerns (e.g., Facility compliance or the like) that may impact the Products. In addition, Sopharma agrees to promptly notify and provide Achieve copies of any request, directive, or other communication to or from any Regulatory Authority related to the Products or their Manufacture . Sopharma shall provide Achieve with a copy of any such correspondence made by Sopharma and its response to any such reports or correspondence from the applicable Regulatory Authority for review and comment prior to submission to the applicable Regulatory Authority, and Sopharma shall incorporate in good faith any recommendations provided by Achieve with respect thereto prior to submitting such

correspondence or response to the applicable Regulatory Authority. In addition, Sopharma shall notify Achieve of any occurrences or information that arise out of Sopharma's Manufacturing activities that have, or could reasonably be expected to have, adverse regulatory compliance or reporting consequences concerning any Product or which might otherwise be reasonably expected to adversely affect the supply by Sopharma of Products to Achieve. Notwithstanding the foregoing, nothing in this Section 6.5 shall require Sopharma to disclose to Achieve any Sopharma Know-How.

6.6 Changes or Modifications in Manufacturing Activities . Sopharma shall not make any changes to the Specifications, processes, Facilities, raw materials, raw material suppliers or any other item in any manner that would affect the Manufacturing activities related to the Product, without Achieve's prior written approval. Notwithstanding the foregoing, Sopharma shall promptly make and implement such changes as are required by Applicable Law ("**Required Changes**"), after written notice to Achieve, provided that, prior to implementation, all such Required Changes shall be subject to Achieve's written approval, including with respect to the timelines, estimated effect on Price and other issues regarding such implementation. In addition, Achieve shall have the right to request changes in or modifications to the Specifications. All such changes or modifications shall be documented in writing and shall be signed by an authorized representative of Achieve and Sopharma. If such changes or modifications result in a material change in Sopharma's Manufacturing costs or lead times, the Parties shall agree upon an appropriate adjustment to the Price or in the delivery schedules, as the case may be, for Products to be provided by Sopharma hereunder. Sopharma shall promptly implement all such agreed upon changes to the Specifications.

6.7 Deviations and Investigations. In the event that a material deviation occurs during the course of the Manufacture, including Packaging, storage and analytical testing, of any batch of Product for Achieve under this Supply Agreement, Sopharma shall immediately provide Achieve with a detailed written description of any such deviation and undertake all reasonable and appropriate actions to investigate the cause of such deviation and to correct the same. A completed written report of the results of any such investigation will be provided to Achieve for such batch.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES

7.1 Sopharma.

7.1.1 Sopharma represents that:

(a) It has the authority to enter into this Agreement and all rights necessary to perform its obligations hereunder.

(b) As of the Effective Date, there are no claims, judgments or settlements against or owed by Sopharma or its Affiliates, or pending or threatened claims or litigation, relating to the Products or the Sopharma Know-How.

(c) It is not debarred and has not used in any capacity the services of any person debarred under subsection 306(a) or (b) of the U.S. Generic Drug Enforcement Act of 1992, or other Applicable Law. As of the Effective Date, no debarment proceedings against Sopharma or any of its employees or permitted subcontractors have been commenced.

7.1.2 Sopharma warrants that:

(a) The Facility shall comply with this Supply Agreement and all Applicable Law (including cGMPs, if applicable).

(b) All Product supplied hereunder shall comply with this Supply Agreement, all Applicable Law (including cGMPs, if applicable), be free from defects in material and workmanship, and meet all Specifications. Sopharma shall perform and document all Manufacturing activities contemplated herein in compliance with all Applicable Laws.

(c) It will maintain throughout the Term all permits, licenses, registrations and other forms of governmental authorization and approval as required by Applicable Law in order for it to perform its obligations hereunder.

(d) Title to all Product provided under this Supply Agreement shall pass to Achieve as set forth in Section 2, free and clear of any security interest, lien, or other encumbrance.

(e) The Manufacture of Products hereunder will not infringe or misappropriate any intellectual property right of any Third Party.

(f) In performing its obligations hereunder, Sopharma will not use in any capacity the services of any person debarred under subsection 306(a) or (b) of the U.S. Generic Drug Enforcement Act of 1992, or other Applicable Law.

7.2 Achieve.

7.2.1 Achieve represents that it has the authority to enter into this Agreement and all rights necessary to perform its obligations hereunder.

7.2.2 Achieve warrants that it will maintain throughout the Term all permits, licenses, registrations and other forms of governmental authorization and approval as required by Applicable Law in order for Achieve to seek Regulatory Approval for and commercialize the Products in the Territory.

7.2.3 Disclaimer. EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS SET FORTH IN THIS ARTICLE 7, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED OR STATUTORY, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 8
CONFIDENTIALITY

8.1 Confidential Information. "**Confidential Information**" means the terms of this Supply Agreement and any proprietary or non-public information or data disclosed under this Agreement by one Party ("Disclosing Party") to the other Party ("Receiving Party"), including know-how, trade secrets or other information, and excluding information that: (a) is or becomes generally known to the public through no fault of or breach of this Agreement by the Receiving Party; (b) is rightfully known by the Receiving Party at the time of disclosure without an obligation of confidentiality; (c) is independently developed by the Receiving Party without use of the Disclosing Party's Confidential Information; or (d) the Receiving Party rightfully obtains from a third party without restriction on use or disclosure.

8.2 Restrictions. Neither Party will use the other party's Confidential Information except as necessary for the performance of, or as permitted by, this Supply Agreement. Each Party will use all reasonable efforts to maintain the confidentiality of the other Party's Confidential Information, but in no event less than the efforts that such Party ordinarily uses with respect to its own proprietary information of similar importance. The foregoing obligations will not restrict either Party from disclosing Confidential Information of the other Party pursuant to the order or requirement of a court, arbitral body, administrative agency or other governmental body, provided that the Party required to make such a disclosure gives reasonable notice to the other Party to enable it to contest the order or requirement. In addition, each Party may disclose the terms and conditions of this Supply Agreement: (a) as required under applicable securities regulations; (b) on a confidential basis to its legal or financial advisors, and its insurance carriers; and (c) on a confidential basis to present or future acquirers, investors and lenders.

8.3 The Confidentiality obligations set forth in this Article 8 shall continue with regard to an item of Confidential Information throughout the Term of this Agreement and for ten (10) years thereafter; provided that, if the Confidential Information constitutes a trade secret, the obligations hereunder shall survive any termination of this Agreement unless and until one of the exceptions under Section 8.1 applies.

ARTICLE 9
INDEMNIFICATION AND INSURANCE

9.1 Indemnification.

9.1.1 Indemnification by Sopharma . Sopharma hereby agrees to defend, hold harmless and indemnify, to the extent permitted by Applicable Law, (collectively, " **Indemnify** ") Achieve and its Affiliates and their respective directors, officers and employees of such Persons and the respective successors and assigns of any of the foregoing (the "**Achieve Indemnitees** ") from and against any and all liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys' fees and other expenses of litigation) (collectively, "**Liabilities** ") resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a "**Third-Party Claim**") against any Achieve Indemnitees and arising from or occurring as a result of: (a) death or personal injury related to or resulting from the Manufacture of the Products by or on behalf of Sopharma or its Affiliates for the Territory in deviation of the Specifications; (b) any

material breach of any of Sopharma's obligations, representations, warranties or covenants under this Supply Agreement, and (c) the alleged or actual infringement or misappropriation of any Third Party intellectual property right by the development, manufacture, supply or commercialization of the Products in the Territory; provided that Sopharma's obligation to Indemnify the Achieve Indemnitees pursuant to this Section 9.1.1(a)-(b) shall not apply to the extent that any such Liabilities are the result of a material breach by Achieve of its obligations, representations, warranties or covenants under this Supply Agreement or any Achieve Indemnitee's gross negligence or willful misconduct.

9.1.2 Indemnification by Achieve . Achieve hereby agrees to defend, hold harmless and Indemnify Sopharma and its Affiliates and their respective directors, officers and employees and the respective successors and assigns of any of the foregoing (the "**Sopharma Indemnitees**") from and against any and all Liabilities, damages, penalties, fines, cost and expenses (including reasonable attorneys' fees and other expenses of litigation) (collectively Liabilities) resulting suits, claims, actions and demands, from Third-Party Claims against any Sopharma Indemnitee arising from or occurring as a result of: (a) the marketing, distribution or sale of the Products by or on behalf of Achieve or its Affiliates in the Territory; (b) any material breach of any of Achieve's obligations, representations, warranties or covenants under this Supply Agreement; provided that Achieve's obligation to Indemnify the Sopharma Indemnitees pursuant to this Section 9.1.2 shall not apply to the extent that any such Liabilities are the result of a material breach by Sopharma of its obligations, representations, warranties or covenants under this Supply Agreement or any Sopharma Indemnitee's gross negligence or willful misconduct.

9.1.3 Procedure. To be eligible to be Indemnified hereunder, the indemnified Person shall provide the indemnifying Party with prompt written notice of the Third-Party Claim giving rise to the indemnification obligation pursuant to this Section 9.1.3 and the right to control the defense (with the reasonable cooperation of the indemnified Person) or settlement any such claim; provided, however, that the indemnifying Party shall not enter into any settlement that admits fault, wrongdoing or damages without the indemnified Person's written consent, such consent not to be unreasonably withheld or delayed. The indemnified Person shall have the right to join, but not to control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying Party.

9.2 Insurance. Each Party shall procure and maintain insurance, including clinical trials and product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being manufactured, clinically tested in human subjects or commercially distributed or sold by a Party. It is understood that such insurance shall not be construed to create a limit of either Party's liability or indemnification obligations under this Article 9, or that the maintenance of such insurance shall not be construed to relieve either Party of its other obligations under this Agreement. Each Party shall provide the other with written evidence of such insurance upon request. Each Party shall provide the other with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance

ARTICLE 10
TERM AND TERMINATION

10.1 **Term** . The term of this Supply Agreement shall be twenty (20) years from the Effective Date (the "**Term**"), unless it is terminated earlier in accordance with Section 10.2.

10.2 **Termination**. Notwithstanding anything to the contrary herein, this Supply Agreement may be terminated:

10.2.1 In its entirety or with respect to one or more Products, on a Product-by-Product basis, by mutual written consent of Sopharma and Achieve.

10.2.2 In its entirety by a Party if: (i) the other Party has filed a petition in bankruptcy, or if an involuntary petition in bankruptcy has been filed against the other Party and such petition is not dismissed within sixty (60) days, or if a receiver or guardian has been appointed forth over the other Party, or upon or after the cessations of operations of the other Party, or if the other Party compounds with its creditors, or (ii) the other Party commits a material breach of this Agreement and fails to cure such breach within one hundred and eighty (180) days of receipt of written notice.

10.3 **Effects of Termination**. Upon the expiration of the Term or termination of this Supply Agreement, in its entirety or with respect to one or more Products, this Supply Agreement shall, except as otherwise provided in this Section 10.3 or Section 10.5, be of no further force or effect; provided, however, that if this Supply Agreement is terminated with respect to one or more Products, but not all Products, then this Supply Agreement shall continue in full force and effect with respect to the Products for which it is not terminated. Upon expiration or termination of this Supply Agreement with respect to any Product: (1) this Supply Agreement will remain in full force and effect for any orders of said Product placed before termination, and (2) Achieve shall pay for and take over any Packaging for said Product that is already ordered or forecasted by Achieve.

10.4 **Nonexclusive Remedy**. Exercise of any right of termination afforded to either Party under this Supply Agreement (i) shall not prejudice any other legal rights or remedies either Party has against the other with respect to any breach of the terms and conditions of this Supply Agreement, and (ii) shall be without any obligation or liability arising from such termination other than such obligations expressly arising from termination of this Supply Agreement.

10.5 **Survival**. All provisions of this Agreement shall terminate upon expiration or termination of this Agreement, provided that Article 4 (Product Acceptance), Article 8 (Confidentiality), Article 9 (Indemnification and Insurance), Article 11 (Disputes), Article 12 (Miscellaneous), and Sections 3.3 (Recordkeeping), 6.2, 6.3, 6.4, 6.5, 7.1.2 (Product Warranties), 7.2.3 (Disclaimer), 10.3 (Effects of Termination), 10.4 (Nonexclusive Remedy), and 10.5 (Survival) shall survive any expiration of the Term or termination of this Supply Agreement.

ARTICLE 11
DISPUTE RESOLUTION

11.1 Each Party will appoint an individual employed by it to serve as its "Principal Contact" for purposes of this Agreement. Either Party may from time to time replace its Principal Contact with a different employee upon reasonable written notice. The two Principal Contacts shall communicate with each other regularly during the Term as the Parties may agree or as the Principal Contacts shall mutually determine to be useful.

11.2 The Parties intend that, to the maximum extent practicable, they shall reach decisions hereunder cooperatively through discussions among the Principal Contacts and by mutual consent of the Parties. In situations in which that does not occur, disputes or differences arising out of or in connection with this Agreement shall initially be referred for review by the Parties' respective Senior Managements (as defined below). Such Senior Managements shall discuss the proposed dispute or difference, and shall meet with respect thereto if either of them believes a meeting or meetings are likely to be useful. If the Senior Managements do not resolve the dispute or difference within thirty (30) days (or such lesser or longer period as they may agree is a useful period for their discussions), then either Party may pursue its other available remedies, consistent with this Agreement. As used herein, Sopharma's "Senior Management" means its then-current CEO, and Achieve's "Senior Management" means its then-current CEO.

11.3 If the Senior Managements are not able to resolve such dispute referred to them under Section 11.2 within such thirty (30) day period, then the dispute shall be resolved by final and binding arbitration according to the Commercial Arbitration Rules and Mediation Procedures of the American Arbitration Association ("AAA Rules").

11.3.1 The Parties shall select a mutually agreeable arbitrator who has significant relevant experience in the subject matter of the disputed issue and no affiliation or pre-existing relationship with either Party. If the Parties cannot agree on an arbitrator within ten (10) days after the end of the ten (10) day period referred to in Section 11.2, either Party may request appointment of an arbitrator on behalf of the Parties in accordance with AAA Rules, and the proceeding shall be conducted in accordance with AAA Rules. The arbitration will take place in New York, New York, and will be conducted in English. The arbitrator may decide any issue as to whether, or as to the extent to which, any dispute is subject to the arbitration and other dispute resolution provisions in this Agreement. The arbitrator must base the award on the provisions of this Agreement and must render the award in a writing which must include an explanation of the reasons for such award. In addition, for the matters to be settled as set forth in Sections 2.8.1(c)(ii) and 3.2.2, the arbitrator shall follow the rules set forth in Section 11.3.2. Judgment upon the award rendered by the arbitrator may be entered by any court having jurisdiction thereof. Subject to Section 11.3.2, the arbitrator's fees and expenses shall be shared equally by the Parties, unless the arbitrator in the award assesses such fees and expenses against one of the Parties or allocates such fees and expenses other than equally between the Parties. Each Party shall bear and pay its own expenses incurred in connection with any dispute resolution under this Section 11.3. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrator hereunder or pending the arbitrator's decision of the dispute subject to arbitration.

11.3.2 Within ten (10) days after the selection of the arbitrator, each Party shall submit to the arbitrator and the other Party a detailed written proposal to resolve the matter described in 2.8.1(c)(ii) and/or 3.2.2, as applicable (each a "**Proposal**"). Within ten (10) days after the delivery of the last Proposal to the arbitrator, each Party may submit written observations regarding other Party's Proposal. The Parties shall not have the right to call any witnesses in support of their arguments, nor compel any production of documents or take any discovery from the other Party. Neither Party may have any other communications (either written or oral) with the arbitrator other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section 11.3.2; provided that, the arbitrator may convene a hearing if the arbitrator so chooses to ask questions of the Parties regarding their respective Proposals. Within ten (10) days after the arbitrator's appointment, the arbitrator will select one of the two Proposals (without modification) provided by the Parties that he or she believes is most consistent with the intention underlying and agreed principles set forth in this Agreement and most accurately reflects industry norms for a transaction of this type. The decision of the arbitrator shall be final, binding, and unappealable and the Parties shall promptly amend this Supply Agreement to incorporate the terms set forth in the Proposal selected by the arbitrator. If a Party fails to submit a Proposal within ten (10) days after the selection of the arbitrator, the arbitrator shall select the Proposal of the other Party as the resolution of the dispute. Any time period set forth in this Section 11.3.2 may be extended by mutual agreement of the Parties. The arbitrator's fees and expenses shall be shared equally by the Parties, and each Party shall bear and pay its own expenses incurred in connection with any dispute resolution under this Section 11.3.2, unless the arbitrator determines that a Party has incurred unreasonable fees and/or expenses due to vexatious or bad faith positions taken by the other Party, in which event the arbitrator may make an award of all or any portion of such fees and/or expenses so incurred.

ARTICLE 12
MISCELLANEOUS

12.1 **Interpretation**. Article, Section and clause headings in this Supply Agreement are intended for convenience or reference and shall be given no effect in the interpretation of this Agreement. Unless context clearly requires otherwise, whenever used in this Supply Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Supply Agreement (including any Exhibits); (iv) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing; (v) words using the singular or plural form also include the plural or singular form, respectively.

12.2 **Expenses**. Except as otherwise expressly provided herein, each Party shall bear its own costs, fees and expenses incurred by such Party in connection with this Supply Agreement.

12.3 **Licenses and Permits**. Each Party shall, at its sole cost and expense, maintain in full force and affect all necessary licenses, permits, and other authorizations required by Applicable Law in order to carry out its duties and obligations hereunder.

12.4 **Force Majeure** . No Party shall be liable for a failure or delay in performing any of its obligations under this Supply Agreement to the extent that such failure or delay is solely due to causes beyond the reasonable control of the affected Party, including: (a) acts of God; (b) fire, explosion, or unusually severe weather, including but not limited to flooding, drought, storms, hail, extreme temperature changes; (c) war, invasion, riot, terrorism, or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargo or blockages; (e) national or regional emergency; (f) strikes or industrial disputes at a national level which directly impact the affected Party's performance under this Supply Agreement; or (g) other similar cause outside of the reasonable control of such Party ("**Force Majeure**"); provided that the Party affected shall promptly notify the other of the Force Majeure condition and shall use Commercially Reasonable Efforts to eliminate, cure or overcome any such causes and resume performance of its obligations as soon as possible. If the performance of Sopharma's obligation to supply Product under this Supply Agreement is delayed owing to a Force Majeure for any continuous period of more than ninety (90) days, then Section 2.8.1(c)(i) through (iii) shall apply. If the performance of any obligation of a Party under this Supply Agreement is delayed owing to a Force Majeure for any continuous period of more than one hundred eighty (180) days, the other Party shall have the right to terminate this Supply Agreement.

12.5 Neither Party may assign or transfer this Supply Agreement, including by merger, operation of law, or otherwise, without the other Party's prior written consent (which shall not be withheld unreasonably) except that each Party may assign this Supply Agreement without the other Party's consent in the case of assignment or transfer to a Third Party that succeeds to all or substantially all of the assigning Party's business and assets relating to the subject matter of this Supply Agreement, whether by sale, merger, operation of law or otherwise. Any attempted assignment by a Party in violation of this Section 12.5 without the written consent of the other Party will be null and void. Except as above limited, this Supply Agreement is binding upon and will inure to the benefit of each of the Parties, its successors and assigns. Without limiting the foregoing, in the event that a Party is acquired, the acquiring Party shall agree in writing to abide by the terms of this Supply Agreement.

12.6 This Supply Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, between the Parties with respect to its subject matter. Notwithstanding the above, the License Agreement shall survive in full force and effect, provided that, in case of inconsistencies between this Supply Agreement and the License Agreement, this Supply Agreement shall govern. For clarity, the Parties hereby explicitly agree that this Supply Agreement supersedes the Commercial Agreement between the Parties as of the Effective Date.

12.7 All notices, requests or other communication provided for or permitted hereunder shall be given in writing and shall be hand delivered or sent by confirmed facsimile, reputable courier or by registered or certified mail, postage prepaid, return receipt requested, to the address set forth on the signature page of this Supply Agreement, or to such other address of which either Party may inform the other in writing. Notices will be deemed delivered on the earliest of transmission by facsimile, actual receipt or seven days after mailing as described herein.

12.8 This Agreement may be amended, modified or waived only in a writing signed by the Party or Parties to be bound thereby.

12.9 If any provision of this Supply Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and the Parties' fundamental intentions hereunder, and the remaining provisions shall not be affected or impaired.

12.10 Nothing herein shall constitute a joint venture agreement and, except as expressly set forth herein, nothing herein shall make a Party a partner, principal or agent of the other. Except as expressly set forth herein, a Party shall not have the authority to bind the other Party in any respect whatsoever to Third Parties.

12.11 This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to any conflict of laws rules to the contrary.

12.12 This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

[*The remainder of this page is left intentionally blank.*]

IN WITNESS WHEREOF, the Parties have caused this Supply Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

SOPHARMA AD		**ACHIEVE LIFE SCIENCE, INC.**	
By:	/s/ Ognian Donev	By:	/s/ Richard Stewart
Name:	Ognian Donev	Name:	Richard Stewart
Title:	CEO	Title:	Chairman & CEO

16, Iliensko shosse str.
1220 Sofia, Bulgaria

30 Sunnyside Avenue
Mill Valley CA 94941

EXHIBIT 1

PRODUCTS AND PRICES

Active Agent Product(s)	Strength/Form	Supply Price Ex Works (Euro) per kg	Minimum Order Quantity in kg
Cytisine	Active product ingredient	[***]	[***]

Finished Product(s)	Strength/Form	No of blisters of 10 per pack	Price per finished packs 100	Minimum Order Quantity
Tabex	1.5 mg coated tablet	10 (9 blisters of 10 tablets, 1 blister of 11 tablets)	[***]	[***]

The Prices for the Finished Product(s) include the following costs:

- Color of blister: printing using 1 color
- Color of Packaging: printing using 3 colors
- Color of insert leaflet: printing using 1 color

The Supply Price for Bulk API and Finished Product to be supplied is subject to annual increase on April 1st of each year, based on the Producer Price Index for the European Union as published by the Organisation for Economic Co-Operation and Development (OECD) for the prior calendar year, such increase not to exceed [***]% but not less than [***]% in any one calendar year.

FACILITY

SOPHARMA'S TABLETING FACILITY: [_____]

*****Confidential Treatment Requested.**

Exhibit 31.1

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

I, Richard Stewart, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 31.2

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

I, John Bencich, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2017

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

Exhibit 32.1

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the three and nine months ended September 30, 2017 (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 9, 2017

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

Exhibit 32.2

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the three and nine months ended September 30, 2017 (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 9, 2017

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