# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

1	м	21	rk	n	n	a۱

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

For the quarterly period ended June 30, 2021

ΩR

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

FOR THE TRANSITION PERIOD FROM

Commission File Number 001-38792

# Alector, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

131 Oyster Point Blvd, Suite 600 South San Francisco, California (Address of principal executive offices) 82-2933343

(I.R.S. Employer Identification No.)

94080

ive offices) (Zip Code)
Registrant's telephone number, including area code: 415-231-5660

#### Not applicable

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	ALEC	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

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

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

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

=			
Large accelerated filer	$\boxtimes$	Accelerated filer	
Non-accelerated filer		Smaller reporting company	
Emerging growth company			

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

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

As of July 30, 2021, the registrant had 80,875,423 shares of common stock, \$0.0001 par value per share, outstanding.

# Alector, Inc.

# **Table of Contents**

		Page
PART I.	FINANCIAL INFORMATION	
Item 1.	<u>Financial Statements</u>	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4.	Controls and Procedures	21
PART II.	OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	Risk Factors	23
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	69
Item 6.	<u>Exhibits</u>	70
	Signatures	71
	<del></del>	

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other

similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements about: our plans relating to the development and manufacturing of our product candidates and research programs; the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results; the timing and focus of our future clinical trials, and the reporting of data from those trials; П the impact of the coronavirus (COVID-19) pandemic on our business; our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy; the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise; our estimates of the number of patients in the United States who suffer from the diseases we are targeting and the number of patients that will enroll in our clinical trials; the size of the market opportunity for our product candidates in each of the diseases we are targeting; our ability to expand our product candidates into additional indications and patient populations; П the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates; the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates for various diseases; our ability to obtain and maintain regulatory approval of our product candidates; our plans relating to the further development and manufacturing of our product candidates, including additional indications that we may pursue; existing regulations and regulatory developments in the United States and other jurisdictions;

the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements.

the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;

our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;

candidates for preclinical studies and clinical trials;

our financial performance; and

the need to hire additional personnel and our ability to attract and retain such personnel;

our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this report and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report on Form 10-Q, whether as a result of any new information, future events, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website (https://investors.alector.com), Securities and Exchange Commission (SEC) filings, webcasts, press releases, and conference calls. We use these mediums, including our website, to communicate with our stockholders and public about our company, our products, and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

# PART I—FINANCIAL INFORMATION

#### Item 1. Financial Statements.

# ALECTOR, INC.

# Condensed Consolidated Balance Sheets (Unaudited)

(In thousands, except share and per share data)

	June 30, 2021	D	ecember 31, 2020
Assets			
Current assets:			
Cash and cash equivalents	\$ 125,713	\$	49,969
Marketable securities	193,857		363,339
Prepaid expenses and other current assets	9,760		8,203
Total current assets	329,330		421,511
Property and equipment, net	28,701		30,181
Operating lease right-of-use assets	31,617		32,470
Restricted cash	1,472		1,472
Other assets	 5,993		2,617
Total assets	\$ 397,113	\$	488,251
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	11,942	\$	3,004
Accrued clinical supply costs	7,174		11,148
Accrued liabilities	22,100		22,538
Deferred revenue, current portion	25,417		23,886
Operating lease liabilities, current portion	 7,760		7,512
Total current liabilities	74,393		68,088
Deferred revenue, long-term portion	96,208		108,417
Operating lease liabilities, long-term portion	41,839		43,744
Other long-term liabilities	 158		472
Total liabilities	212,598		220,721
Stockholders' equity:	_		
Common stock, \$0.0001 par value; 200,000,000 shares authorized; 80,005,162 and			
79,316,261 shares issued and outstanding as of June 30, 2021 and			
December 31, 2020	8		8
Additional paid-in capital	701,670		676,956
Accumulated other comprehensive income	203		614
Accumulated deficit	 (517,366)		(410,048)
Total stockholders' equity	 184,515		267,530
Total liabilities and stockholders' equity	\$ 397,113	\$	488,251

# Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except share and per share data)

	Three Mon June	ıded	Six Months Ended June 30,				
	 2021		2020		2021		2020
Collaboration revenue	\$ 6,568	\$	3,170	\$	10,678	\$	10,341
Operating expenses:							
Research and development	47,818		34,062		93,551		68,667
General and administrative	14,075		15,697		25,087		30,341
Total operating expenses	 61,893		49,759		118,638		99,008
Loss from operations	 (55,325)		(46,589)		(107,960)		(88,667)
Other income, net	178		1,263		642		3,322
Net loss	 (55,147)		(45,326)		(107,318)	,	(85,345)
Unrealized gain (loss) on marketable securities	(207)		(936)		(411)		1,704
Comprehensive loss	\$ (55,354)	\$	(46,262)	\$	(107,729)	\$	(83,641)
Net loss per share, basic and diluted	\$ (0.69)	\$	(0.58)	\$	(1.35)	\$	(1.11)
Shares used in computing net loss per share, basic and diluted	 79,790,036		78,415,195		79,598,188	-	76,617,938

# Condensed Consolidated Statement of Stockholders' Equity (Unaudited)

(In thousands, except share data)

	Communication	C4	Accumulated Additional Other Paid-In Comprehensive Accumulated Stock Capital Income Deficit		Total Stockholders' Equity				
	Shares	11 310	Amount	-	Сарітаі	 Ilicollie	 Delicit		Equity
Balance — December 31, 2020	79,316,261	\$	8	\$	676,956	\$ 614	\$ (410,048)	\$	267,530
Exercise of stock options	415,386				3,874	_	_		3,874
Stock-based compensation	_		_		8,800	_	_		8,800
Unrealized loss on marketable									
securities	_					(204)	_		(204)
Net loss	_		_		_	_	(52,171)		(52,171)
Balance — March 31, 2021	79,731,647		8		689,630	410	(462,219)		227,829
Exercise of stock options	207,453		_		1,993	_	_		1,993
Purchase of common stock under employee stock purchase plan	84,105		_		969	_	_		969
Forfeiture of restricted common stock	(18,043)				_		_		_
Stock-based compensation	(10,045)				9,078		_		9,078
Unrealized loss on marketable					3,070				5,070
securities	_		_		_	(207)	_		(207)
Net loss	_				_		(55,147)		(55,147)
Balance — June 30, 2021	80,005,162	\$	8	\$	701,670	\$ 203	\$ (517,366)	\$	184,515

# Condensed Consolidated Statement of Stockholders' Equity (Unaudited)

(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income		Accumulated Deficit		Total Stockholders' Equity			
	Shares	A	mount								
Balance — December 31, 2019	69,052,873	\$	7	\$	414,414	\$	142	\$	(219,820)	\$	194,743
Issuance of common stock upon follow-on public offering, net of											
issuance costs of \$1,148	9,602,500		1		224,510		_		_		224,511
Exercise of stock options	361,096		_		3,217		_		_		3,217
Stock-based compensation	_		_		6,642		_		_		6,642
Unrealized gain on marketable											
securities	_		_		_		2,640		_		2,640
Net loss	_		_		_		_		(40,019)		(40,019)
Balance — March 31, 2020	79,016,469		8		648,783		2,782		(259,839)		391,734
Exercise of stock options	190,709		_		2,196		_		_		2,196
Purchase of common stock under	45,217				715						715
employee stock purchase plan	45,217		<del></del>						<u> </u>		
Stock-based compensation Unrealized loss on marketable					6,948		_				6,948
securities	_		_		_		(936)		_		(936)
Net loss	_		_		_		_		(45,326)		(45,326)
Balance — June 30, 2020	79,252,395	\$	8	\$	658,642	\$	1,846	\$	(305,165)	\$	355,331

# Condensed Consolidated Statements of Cash Flows (Unaudited) (In thousands)

		Six Months Ended June 30,				
		2021	_	2020		
Cash flows from operating activities:						
Net loss	\$	(107,318)	\$	(85,345)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		3,130		2,903		
Stock-based compensation		17,878		13,590		
Amortization of premiums and accretion of discounts on marketable securities		1,152		(250)		
Amortization of right-of-use assets		938		608		
Loss from disposal of property and equipment, net		_		9		
Changes in operating assets and liabilities:						
Prepaid expenses and other current assets		(1,557)		(2,084)		
Other assets		(3,376)		(967)		
Accounts payable		9,148		4,431		
Accrued liabilities and accrued clinical supply costs		(4,225)		519		
Deferred revenue		(10,678)		(10,341)		
Lease liabilities		(2,014)		(1,328)		
Other long-term liabilities		(314)		<u>—</u>		
Net cash used in operating activities		(97,236)		(78,255)		
Cash flows from investing activities:						
Purchase of property and equipment		(1,775)		(3,863)		
Purchase of marketable securities		(5,081)		(307,388)		
Maturities of marketable securities		173,000		161,635		
Net cash provided by (used in) investing activities		166,144		(149,616)		
Cash flows from financing activities:						
Proceeds from issuance of common stock upon follow-on public offering, net of issuance costs		_		224,603		
Proceeds from the exercise of options to purchase common stock		5,867		5,413		
Purchase of common stock under employee stock option plan		969		715		
Net cash provided by financing activities		6,836		230,731		
Net increase in cash, cash equivalents, and restricted cash	<u></u>	75,744		2,860		
Cash, cash equivalents, and restricted cash at beginning of period		51,441		91,113		
Cash, cash equivalents, and restricted cash at ord period	\$	127,185	\$	93,973		
	<u> </u>	127,103	Ψ	33,373		
Non-cash investing and financing activities:						
Property and equipment purchases included in accounts payable and accrued liabilities	\$	348	\$	184		

# ALECTOR, INC. Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 1. The Company and Liquidity

Alector, Inc. (Alector or the Company) is a Delaware corporation headquartered in South San Francisco, California. Alector is a clinical stage biopharmaceutical company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegeneration.

#### Follow-on Offering

On January 30, 2020, the Company completed a follow-on offering through issuing and selling 9,602,500 shares of common stock at a public offering price of \$25.00 per share, including 1,252,500 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, resulting in aggregate net proceeds of \$224.5 million, after deducting underwriting discounts and commissions and offering costs.

#### 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

The condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (GAAP) as defined by the Financial Accounting Standards Board (FASB). In the opinion of management, these unaudited condensed consolidated financial statements include all normal, recurring adjustments that are necessary to present fairly the results of the interim periods presented. The condensed consolidated financial statements include the accounts of Alector, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 25, 2021.

#### **Use of Estimates**

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expense during the reporting period. The Company evaluates its estimates, including those related to revenue recognition, manufacturing accruals, clinical accruals, fair value of assets and liabilities, income taxes uncertainties, stock-based compensation, and related assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

## Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and short-term marketable securities. Cash and cash equivalents are deposited in checking and sweep accounts at a financial institution. Such deposits may, at times, exceed federally insured limits.

#### Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are no significant unrealized gains or losses on the money market funds for the periods presented.

Restricted cash as of June 30, 2021 relates to a letter of credit established for a lease entered into in June 2018.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

		Six Months Ended June 30,					
	' <u>-</u>	2021					
	' <u>-</u>						
Cash and cash equivalents	\$	125,713	\$	92,501			
Restricted cash		1,472		1,472			
Total cash, cash equivalents, and restricted cash	\$	127,185	\$	93,973			

#### Fair Value of Financial Instruments

The Company's financial instruments include cash and cash equivalents, marketable securities, accounts payable, and accrued liabilities. The Company's financial instruments approximate fair value due to their relatively short maturities.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 — Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

*Level 3* – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

#### Revenue Recognition

The Company entered into an agreement in October 2017 with AbbVie Biotechnology, Ltd. (AbbVie) to co-develop antibodies to two program targets in preclinical development (AbbVie Agreement). Under the terms of the AbbVie Agreement, AbbVie made \$205.0 million in upfront payments, of which \$5.0 million and \$200.0 million was received by the Company in October 2017 and January 2018, respectively. The Company will perform research and development services for the antibodies to the two programs through the end of Phase 2 clinical trials which the Company expects to conduct through 2023. AbbVie will then have the exclusive right to exercise an option to enter into a license and collaboration agreement with the Company for one or both of the programs for \$250.0 million each. If AbbVie exercises its option for the programs, AbbVie will take over the development of the product candidates for such program and costs will be split between the parties. The Company will also share in profits and losses upon commercialization of any products from such program. However, following AbbVie's exercise of its option for a program, the Company may opt out of sharing in development costs and profits or losses for that program and instead receive tiered royalties. Additionally, under the terms of the AbbVie Agreement, the Company will be eligible to earn up to an additional \$242.8 million in milestone payments per program related to the initiation of certain clinical studies and regulatory approval for up to three indications per program. The Company assessed its collaboration agreement with AbbVie in the context of the delivery of the research and development services.

The Company recognizes collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, the Company measures actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. The Company reevaluates the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. Clinical trials are expensive and can take many years to complete, and the outcome is inherently

uncertain. Changes in the Company's forecasted costs are likely to occur over time based upon changes in clinical trial procedures set forth in protocols, changes in estimates of manufacturing costs, or feedback from regulators on the design or operation of clinical trials. The Company has had changes to the overall expected costs to satisfy the performance obligations from period to period. For the three months ended June 30, 2021, the Company had a 1% increase in the forecast of the total expected costs. For the three months ended June 30, 2021, the increase in the overall expected costs to satisfy the performance obligation resulted in an approximately \$0.7 million reduction in revenue compared to if the expected costs had remained the same, as a result of the cumulative catch up for the change in estimate. Collaboration revenue under the Company's collaboration agreement with AbbVie during the three and six months ended June 30, 2021was \$6.6 million and \$10.7 million, respectively, the entire amount of which was included in deferred revenue at the beginning of the period. The deferred revenue was \$121.6 million as of June 30, 2021. The deferred revenue is expected to be recognized over the research and development period of the programs through the completion of Phase 2 clinical trials.

The Company entered into an agreement in March 2020 with Innovent Biologics (Innovent) to license, develop, and commercialize AL008 in China (Innovent Agreement). AL008 is the Company's novel antibody targeting the CD47-SIRP-alpha pathway, a potent survival pathway co-opted by tumors to evade the innate immune system. Under the terms of the Innovent Agreement, Innovent may pay the Company up to \$11.5 million in development milestones, \$112.5 million in sales milestones, and future royalties for any sales. The Company retains the rights to develop and commercialize AL008 outside of China. The Company has determined there is one performance obligation for the delivery of the license and will recognize revenue when it is probable that there will not be significant reversal of cumulative revenue. Development and sales milestones under the Innovent Agreement have not been included in the transaction price, as all these amounts were fully constrained as of June 30, 2021. As of June 30, 2021, no revenue has been recognized or payments received under the Innovent Agreement.

#### Stock-based Compensation

Stock-based compensation is measured on the grant date based on the fair value of the awards. The fair value of options to purchase common stock are measured using the Black-Scholes option-pricing model. Stock-based compensation associated with restricted stock units (RSUs) is based on the fair value of the Company's common stock on the grant date, which equals the closing price of the Company's common stock on the grant date. The Company recognizes expense over the vesting period of the awards. Expense for options and RSUs are recognized on a straight-line basis.

The Company also granted RSUs with market conditions to certain executives. The fair value of the RSUs with market conditions are estimated using a Monte Carlo simulation model. Assumptions and estimates utilized in the model include the stock price on grant date, risk-free interest rate, dividend yield, expected stock volatility, and the estimated period to achieve the market condition. The expense is recognized based on continued employment of the participants, regardless of achievement of the market condition. Expense related to the RSUs with market conditions is recognized using the accelerated attribution method. The Company accounts for forfeitures as they occur for all awards.

#### Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are the result of transactions and economic events other than those with stockholders. The Company's only element of other comprehensive loss was net unrealized gain (loss) on marketable securities.

#### 3. Fair Value Measurements

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy:

		June 30, 2021										
	Fair Value Hierarchy	Amortized Cost		Unrealized Gains		Unrealized Losses		Fa	air Market Value			
				(In th	ousands)							
Money market funds	Level 1	\$	96,434	\$	_	\$	_	\$	96,434			
U.S. government treasury securities	Level 1		193,654		207		(4)		193,857			
Total cash equivalents and marketable securities		\$	290,088	\$	207	\$	(4)	\$	290,291			

		December 31, 2020										
	Fair Value Hierarchy	Amortized Cost		Unrealized Gains		Unrealized Losses		Fa	air Market Value			
				(In th	ousands)							
Money market funds	Level 1	\$	37,951	\$	_	\$	_	\$	37,951			
U.S. government treasury securities	Level 1		357,725		620		(6)		358,339			
Corporate bonds	Level 2		5,000	\$	_	\$	_		5,000			
Total cash equivalents and marketable securities		\$	400,676	\$	620	\$	(6)	\$	401,290			

The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models for which all significant inputs are observable. The Company classifies marketable securities available to fund current operations as current assets. As of June 30, 2021, the remaining contractual maturities of \$261.0 million of investments were less than one year and \$29.3 million of investments were after one year through two years. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is highly unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. As of June 30, 2021, the Company considered any unrealized losses on our marketable securities to be driven by factors other than credit risk.

### 4. Stock-based Compensation

The Company recognized stock-based compensation as follows:

	Three Months Ended June 30, June 30,								
		2021		2020	2021 2020				
		(In thou	sands)			(In tho	usands)		
Research and development	\$	5,051	\$	3,462	\$	9,488	\$	6,573	
General and administrative		4,027		3,486		8,390		7,017	
Total stock-based compensation	\$	9,078	\$	6,948	\$	17,878	\$	13,590	

#### 2019 Equity Incentive Plan

On January 1, 2021, the Company added 3,965,813 shares to the shares reserved for issuance under the 2019 Equity Incentive Plan (2019 Plan). As of June 30, 2021, the Company had reserved 18,989,234 shares of common stock for issuance under the 2019 Plan, of which 5,514,946 shares were available for issuance.

Activity for the options to purchase common stock shown below (in thousands, except share and per share amounts):

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	12,654,998	\$ 13.96		
Granted	986,213	18.06		
Exercised	(622,839)	9.44		
Forfeited	(815,969)	13.78		
Outstanding as of June 30, 2021	12,202,403	\$ 14.54	8.4	\$ 85,009
Exercisable as of June 30, 2021	4,588,394	\$ 14.13	7.9	\$ 33,816
Vested and expected to vest as of June 30, 2021	12,202,403	\$ 14.54	8.4	\$ 85,009

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money. As of June 30, 2021, total unrecognized stock-based compensation related to unvested stock options was \$71.8 million, which the Company expects to recognize over a remaining weighted-average period of 2.1 years.

#### Restricted Stock Activity

Activity for the restricted stock awards and RSUs is shown below. In May 2021, the Company issued RSUs with market conditions to certain executives, which are included in the table below. The RSUs with market conditions are earned based on stock price performance and continued service by the employee.

	Number of Awards and Units	 Weighted Average Grant Date Fair Value per Share
Unvested restricted stock awards and restricted stock units as of December 31, 2020	186,425	\$ 6.95
Granted	1,305,345	14.80
Vested	(143,640)	6.95
Forfeited	(51,503)	13.06
Unvested restricted stock awards and restricted stock units as of June 30, 2021	1,296,627	\$ 14.61

As of June 30, 2021, total unrecognized stock-based compensation related to unvested restricted stock awards and restricted stock units was \$18.0 million, which the Company expects to recognize over a remaining weighted-average period of 2.7 years.

## 2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (2019 ESPP) enables eligible employees of the Company to purchase shares of common stock at a discount. As of June 30, 2021, the Company has reserved for issuance 2,439,958 shares of common stock pursuant to the 2019 ESPP. Each offering period is approximately six months long. 2019 ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the first trading day of the offering period or (2) the fair market value of the common stock on the purchase date.

#### 5. Related Party Transactions

The Company has a collaboration agreement with Adimab, LLC (Adimab) under which the Company is developing antibodies discovered by Adimab in its AL001 and AL101 product candidates, and the Company is developing antibodies optimized by Adimab in its AL002 and AL003 product candidates (2014 Adimab Agreement). In August 2019, the Company signed a new collaboration agreement with Adimab for research and development of additional

antibodies (2019 Adimab Agreement). The Chief Executive Officer of Adimab is a Co-founder and Chairperson of the board of directors of Alector. For the three and six months ended June 30, 2021, the Company incurred expenses of zero and \$1.0 million for a milestone payment for first patient dosed in the AL002 Phase 2 trial, respectively. For the three and six months ended June 30, 2020, the Company incurred no expenses under the Adimab Agreements. The Company had no accrued liabilities due to Adimab as of three months ended June 30, 2021 and December 31, 2020. Under the 2014 Adimab Agreement, the Company will owe up to \$3.5 million in milestone payments per program to Adimab for its product candidates. The Company will also owe low- to mid- single-digit royalty payments for commercial sales of such product candidates. Under the 2019 Adimab Agreement, the Company will owe certain milestone payments per program for its product candidates and low single-digit royalty payments for commercial sales of such product candidates.

#### 6. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	Three and Six M June 3	
	2021	2020
Restricted stock and restricted stock units subject to future vesting	1,296,627	606,670
Options to purchase common stock	12,202,403	9,440,785
Shares committed under 2019 ESPP	59,413	25,822
Total	13,558,443	10,073,277

#### 7. Subsequent Event

On July 1, 2021, the Company entered into a Collaboration and License Agreement with Glaxo Wellcome UK Limited, a subsidiary of GlaxoSmithKline plc (GSK), pursuant to which Alector and GSK will collaborate on the global development and commercialization of progranulinelevating monoclonal antibodies, AL001 and AL101 (GSK Agreement).

The consummation of the GSK Agreement is subject to obtaining any necessary consents and approvals, including review by the appropriate regulatory agencies under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Act).

Following the consummation of the GSK Agreement, Alector will receive \$700 million in upfront payments, \$500 million expected to be paid in the third quarter of 2021 and \$200 million expected to be paid in the first quarter of 2022. In addition, based on the development and commercialization plan for AL001 and AL101, Alector will be eligible to receive up to an additional \$1.5 billion in clinical development, regulatory, and commercial launch-related milestone payments. In the United States, Alector and GSK will equally share profits and losses from commercialization of AL001 and AL101. Outside of the United States, Alector will be eligible for double-digit tiered royalties.

Alector and GSK will jointly develop AL001 and AL101. Alector will lead the global clinical development of AL001 and AL101, other than with respect to Phase 3 clinical studies for Alzheimer's disease and Parkinson's disease and other non-orphan indications, which will be led by GSK. Alector and GSK will share development costs 60% by GSK and 40% by Alector, except that Alector will solely bear the development costs of the initial Phase 2 clinical studies under the development plan, and the parties will share manufacturing development costs equally.

In the United States, Alector and GSK will be jointly responsible for commercialization of AL001 and AL101, with Alector leading the commercialization for orphan indications and GSK leading the commercialization for Alzheimer's disease and Parkinson's disease and other non-orphan indications. Outside of the United States, GSK will be responsible for commercialization of AL001 and AL101 for all indications.

Alector may opt out of the sharing of development costs and of profit and losses from commercialization in the United States on a product-by-product basis. In such case, Alector will no longer conduct development or commercialization of that product and Alector will receive royalties on net sales in the United States instead of a share of profits.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors" included elsewhere in this report.

#### Overview

We are a clinical stage biopharmaceutical company pioneering immuno-neurology, a novel therapeutic approach for the treatment of neurodegeneration. Immuno-neurology targets immune dysfunction as a root cause of multiple pathologies that are drivers of degenerative brain disorders. We are developing therapies designed to simultaneously counteract these pathologies by restoring healthy immune function to the brain. Supporting our scientific approach, our Discovery Platform enables us to advance a broad portfolio of product candidates, validated by human genetics, which we believe will improve the probability of technical success over shorter development timelines. As a result, we have identified over 100 system targets, have advanced four product candidates, AL001, AL002, AL003, and AL101, into clinical development, and continue to develop our research pipeline, including AL044, AL008, and AL009.

AL001, our first product candidate, modulates progranulin (PGRN), a key regulator of immune activity in the brain with genetic links to multiple neurodegenerative disorders, including frontotemporal dementia (FTD), Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis (ALS). AL001 is initially being developed to treat FTD, a severe, rapidly progressing neurodegenerative disorder that affects 50,000 to 60,000 people in the United States and roughly 110,000 people in the European Union, with potentially higher prevalence in Asia and Latin America.

AL001 is initially being developed for the potential treatment of adults at risk for or with symptomatic frontotemporal dementia due to a progranulin gene mutation (FTD-*GRN*). Our AL001 program has successfully demonstrated target engagement and proof-of-mechanism with a well-tolerated safety profile in healthy volunteers and FTD patients in our Phase 1a, Phase 1b, and Phase 2 clinical trials. In July 2020, we advanced AL001 into a global pivotal Phase 3 trial, named INFRONT-3, enrolling at-risk and symptomatic participants with FTD-*GRN*.

On July 1, 2021, we entered into a Collaboration and License Agreement with GSK to collaborate on the global development and commercialization of AL001 and AL101, our second monoclonal antibody aimed at elevating progranulin. The GSK Agreement is subject to obtaining any necessary consents and approvals, including review by the appropriate regulatory agencies under the HSR Act.

Under the terms of the GSK Agreement, Alector will receive \$700 million in upfront payments, \$500 million expected to be paid in the third quarter of 2021 and \$200 million expected to be paid in the first quarter of 2022. In addition, based on the development and commercialization plan for AL001 and AL101, Alector will be eligible to receive up to an additional \$1.5 billion in clinical development, regulatory, and commercial launch-related milestone payments. In the United States, Alector and GSK will equally share profits and losses from commercialization of AL001 and AL101. Outside of the United States, Alector will be eligible for double-digit tiered royalties. Alector will lead the global clinical development of AL001 and AL101, other than with respect to Phase 3 clinical studies for Alzheimer's and Parkinson's disease and other non-orphan indications, which will be led by GSK. Alector and GSK will share development costs 60% by GSK and 40% by Alector, except that Alector will solely bear the development costs of the initial Phase 2 clinical studies under the development plan, and the parties will share manufacturing development costs equally.

On July 29, 2021, we reported twelve month data from our Phase 2 trial of AL001 patients with FTD-*GRN* at the 2021 Alzheimer's Association International Conference (AAIC). The data presentation focused on up to twelve symptomatic FTD-*GRN* patients treated over twelve months in an open-label study designed to assess safety, pharmacokinetics and pharmacodynamics, exploratory biomarkers, and efficacy. AL001 showed a favorable safety profile and rapidly restored progranulin levels to normal ranges in both plasma and cerebrospinal fluid (CSF) for the duration of treatment. Multiple disease-relevant biomarkers of lysosomal function, complement activation, and neuronal health trended toward normalization or remained stable, including: Time-dependent and durable normalization of lysosomal and inflammatory biomarkers over twelve months of treatment compared to baseline and age-matched controls; stable plasma and CSF neurofilament light chain (NfL) levels over 12 months. Volumetric MRI showed a greater than 10% difference in the atrophy rates in favor of AL001 for the whole brain and frontotemporal cortex measures, and an approximately 50% reduction in ventricular enlargement,

relative to a matched control cohort of participants form the Genetic FTD Initiative (GENFI2). Of note, clinical outcome assessments using the CDR® plus NACC FTLD-SB scale found that AL001 treatment slowed clinical progression by 47% compared to the GENFI2 matched control cohort. The GENFI historical control was generated using a propensity score matching based on CDR® NACC FTLD SB at baseline and further refined by matching based on age, NfL levels, and clinical diagnosis at baseline, all done on a blinded basis without access to longitudinal results.

AL101, our second product candidate in our PGRN portfolio, is designed to treat people suffering from more prevalent neurodegenerative diseases including Alzheimer's disease and Parkinson's disease, in addition to FTD. In line with our therapeutic hypothesis for FTD, mutations that moderately reduce the expression levels of PGRN have been shown to increase the risk of developing Alzheimer's disease and Parkinson's disease, and increased PGRN levels have been demonstrated to be protective for these diseases in animal models. We initiated our AL101 clinical study in January 2020, and we expect to start receiving Phase 1a data in 2021.

Our AL002 product candidate is aimed at treating patients with Alzheimer's disease and is being developed in collaboration with AbbVie. According to the United States Centers for Disease Control and Prevention, Alzheimer's disease is a chronic neurodegenerative disease that is the most common cause of dementia, affecting nearly six million Americans in 2020 and that number is projected to rise to nearly 14 million by 2060. Alzheimer's disease is the sixth leading cause of death in the United States. AL002 is focused on modulating check-point receptors on the brain's immune cells, targeting Triggering Receptor Expressed on Myeloid cells 2 (TREM2). AL002 has demonstrated a safety and tolerability profile that supports further development, target engagement, and proof-of-mechanism in the central nervous systems of healthy volunteers in a Phase 1 trial. We initiated a Phase 2 trial evaluating AL002 in patients with early Alzheimer's disease in January 2021.

AL003 is another product candidate designed to treat patients with Alzheimer's disease and is also being developed in collaboration with AbbVie. AL003 focuses on modulating check-point receptors on the brain's immune cells, targeting sialic acid binding Ig-like lectin 3 (SIGLEC 3). AL003 has demonstrated a safety and tolerability profile that supports further development and peripheral target engagement in healthy volunteers in a Phase 1a study. AL003 has also completed enrollment of Alzheimer's disease patients in a Phase1b study that continues to progress.

AL044 targets *MS4A4A*, a major risk gene for Alzheimer's disease that encodes a transmembrane receptor protein that is expressed selectively in microglia in the brain and is associated with control of microglia functionality and potential viability. Now completing preclinical testing, we expect to advance AL044 into first-in-human safety studies in 2022. We own worldwide rights to AL044.

Based on our insights into innate immunity generated through our work in immuno-neurology, we have identified two potential immuno-oncology therapeutics. We believe that products focused on innate immune biology will complement and expand the efficacy of current immuno-oncology drugs that target the adaptive immune system. AL008 is our novel antibody that inhibits the CD47-SIRP-alpha (SIRP $\alpha$ ) pathway, a potent immune checkpoint pathway co-opted by tumors to evade the immune system. AL008 is a potential best-in-class SIRP-alpha inhibitor with a unique dual mechanism of action that non-competitively antagonizes the CD47-SIRP-alpha pathway by inducing the internalization and degradation of the inhibitory receptor on macrophages to relieve immune suppression (a "don't eat me signal") while also engaging Fc gamma receptors to promote immuno-stimulatory pathways that drive anti-tumor immunity. We have entered into a licensing agreement with Innovent to develop and commercialize AL008 in China. Our AL009 product candidate is a first-in-class multi Siglec inhibitor that works to enhance both the innate and adaptive immune system response to tumors by blocking a critical glycan checkpoint pathway that drives immune inhibition. We plan to initially advance AL009 into clinical studies in oncology and believe it could also have potential therapeutic application to neurodegenerative disorders.

We are closely monitoring the evolving impact of COVID-19 and new variants of the virus on our operations and we continue to be committed to our discovery, research, and clinical development plans and timelines. We are aware that the COVID-19 pandemic has impacted the ability of certain clinical sites to maintain scheduled events for clinical study participants due in part to the site's temporary suspension of activities or regional shelter-in-place directives. We intend to continue to collect data from all existing clinical trial participants and to make progress in completing the enrollment across these on-going clinical trials taking into account applicable regulatory, institutional, and government guidance compliance regimes. Any unscheduled changes in study conduct due to COVID-19-related events could negatively impact the integrity, reliability, or robustness of the data from our clinical trials.

Our operations have been financed primarily through the issuance and sale of convertible preferred stock, our collaboration with AbbVie, and issuance of common stock upon the completion of our IPO. We completed our IPO in February 2019, and received \$168.2 million net proceeds, after deducting underwriting discounts and commissions and

offering expenses. We completed a follow-on offering in January 2020 and received \$224.5 million net proceeds, after deducting underwriting discounts and commissions and offering expenses.

To date, we have not had any products approved for sale and have not generated any revenue from product sales nor been profitable. Further, we do not expect to generate revenue from product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one of our product candidates. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We have incurred net losses in each year since inception and expect to continue to incur net losses for the foreseeable future. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were \$55.1 million and \$107.3 million for the three and six months ended June 30, 2021, respectively. Our net losses were \$45.3 million and \$85.3 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$517.4 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

	advance product candidates through preclinical studies and clinical trials;
	pursue regulatory approval of product candidates;
	hire additional personnel;
	continue to operate as a public company;
	acquire, discover, validate, and develop additional product candidates;
	require the manufacture of supplies for our preclinical studies and clinical trials; and
П	obtain, maintain, expand, and protect our intellectual property portfolio.

#### **Components of Results of Operations**

#### Revenue

We have not generated any revenue from product sales and do not expect to do so in the near future. Our revenue to date has been primarily related to the AbbVie Agreement to co-develop product candidates in two programs in clinical development with AbbVie. We recognize revenue related to our research and development grant as the related research services are performed. We recognize revenue from the upfront payments under the AbbVie Agreement over time as the services are provided. Revenues are recognized as the program costs are incurred by measuring actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. In addition to receiving the upfront payments, we may also be entitled to development and regulatory milestone payments, opt-in payments for continued development after proof-of-concept for AL002 and AL003, and other future payments from profit sharing or royalties after commercialization of product candidates from such programs.

Under the terms of our GSK Agreement, Alector will receive \$700 million in upfront payments, \$500 million expected to be paid in the third quarter of 2021 and \$200 million expected to be paid in the first quarter of 2022. In addition, based on the development and commercialization plan for AL001 and AL101, Alector will be eligible to receive up to an additional \$1.5 billion in clinical development, regulatory, and commercial launch-related milestone payments. Alector and GSK will jointly develop AL001 and AL101.

In the United States, Alector and GSK will equally share profits and losses from commercialization of AL001 and AL101. Alector may opt out of the sharing of development costs and of profit and losses from commercialization in the United States on a product-by-product basis. In such case, Alector will no longer conduct development or commercialization of that product and Alector will receive royalties on net sales of the product in the United States instead of a share of profits. Outside of the United States, GSK will be responsible for commercialization of AL001 and AL101 for all indications, and Alector will be eligible for double-digit tiered royalties.

We expect that our revenue for the next several years will be derived primarily from the AbbVie Agreement and the GSK Agreement. The balance of deferred revenue was \$121.6 million as of June 30, 2021, entirely related to the AbbVie Agreement. The deferred revenue is expected to be recognized over the research and development period of the programs through the completion of Phase 2 clinical trials for AL002 and AL003.

#### **Research and Development Expenses**

Research and development expenses account for a significant portion of our operating expenses. We record research and development expenses as incurred. Research and development expenses consist primarily of costs incurred for the discovery and development of our product candidates, which include:

expenses incurred under agreements with third-party contract organizations, preclinical testing organizations, and consultants;
costs related to production of clinical materials, including fees paid to contract manufacturers;
laboratory and vendor expenses related to the execution of preclinical studies and clinical trials;
personnel-related expenses, including salaries, benefits, and stock-based compensation for personnel engaged in research and development functions;
costs related to the preparation of regulatory submissions;
third-party license fees; and
facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense, and other supplies.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, collaborators, and third-party service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed.

Specific program expenses include expenses associated with the development of our most advanced product candidates, AL001 which commenced dosing of the first patient in a pivotal Phase 3 clinical trial, INFRONT-3, and remains in an ongoing Phase 2 clinical trial, AL002, which commenced dosing of the first patient in a Phase 2 clinical trial, and AL003 and AL101, which are in Phase 1 clinical trials. We also have expenses related to the discovery and development of future product candidates and separately tracked expenses related to programs that we expect to move out of preclinical studies and into Phase 1 clinical trials. We do not track personnel or other operating expenses incurred for our research and development programs on a program-specific basis. These expenses primarily relate to salaries and benefits, stock-based compensation, facility expenses, including depreciation, and lab consumables.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, and incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

#### General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for our personnel in executive, legal, finance and accounting, information technology, human resources, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, consulting, and tax services, insurance costs, and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our programs. We also anticipate that we will continue to incur expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of the NASDAQ Stock Market on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services.

#### Other Income, Net

Other income, net consists of interest earned on our cash equivalents and marketable securities and foreign currency transaction gains and losses incurred during the period.

### **Results of Operations**

#### Comparison of the Three Months Ended June 30, 2021 and 2020

	Three Months Ended					D. II
	June 30, 2021 2020			2020	Dollar Change	
			(In	thousands)		
Collaboration revenue	\$	6,568	\$	3,170	\$	3,398
Operating expenses:						
Research and development		47,818		34,062		13,756
General and administrative		14,075		15,697		(1,622)
Total operating expenses		61,893		49,759		12,134
Loss from operations		(55,325)		(46,589)		(8,736)
Other income, net		178		1,263		(1,085)
Net loss	\$	(55,147)	\$	(45,326)	\$	(9,821)

#### Revenue

Collaboration revenue was \$6.6 million for the three months ended June 30, 2021, compared to \$3.2 million for the three months ended June 30, 2020. We recognize revenue from the upfront payments under the AbbVie Agreement over time as the services are provided. Revenues are recognized as the program costs are incurred by measuring actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Changes in estimates for revenue recognized over time are recognized on a cumulative basis. Revenue increased by \$3.4 million, reflecting the level of our cumulative research activities on the AL002 and AL003 programs under the AbbVie Agreement, including a smaller change to the budget this year compared to prior year.

#### Research and Development Expenses

Research and development expenses were \$47.8 million for the three months ended June 30, 2021, compared to \$34.1 million for the three months ended June 30, 2020. The increase of \$13.8 million was driven by expenses increased by \$5.9 million for other early stage programs as we continue to invest in developing our pipeline. In addition, expenses for AL002 increased by \$5.6 million from clinical costs related to continued progression through clinical trials. We also had a \$4.0 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount and issuance of equity grants to employees.

	Three Months Ended June 30,				Dollar	
		2021	2020			Change
			(In	thousands)		
Direct research and development expenses						
AL001	\$	7,120	\$	8,051	\$	(931)
AL101		1,009		1,396		(387)
AL002		7,865		2,287		5,578
AL003		1,359		2,211		(852)
AL044		1,958		3,220		(1,262)
Other early stage programs		10,256		4,320		5,936
Indirect research and development expenses						
Personnel related (including stock-based compensation)		13,795		9,775		4,020
Facilities and other unallocated research and development						
expenses		4,456		2,802		1,654
Total research and development expenses	\$	47,818	\$	34,062	\$	13,756

#### General and Administrative Expenses

General and administrative expenses were \$14.1 million for the three months ended June 30, 2021, compared to \$15.7 million for the three months ended June 30, 2020. The decrease of \$1.6 million was driven by a \$2.6 million decrease in legal expense due to arbitration costs ending in 2020. This was offset by a \$0.8 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount and issuance of equity grants to employees.

#### Other Income, Net

Other income, net was \$0.2 million for the three months ended June 30, 2021, compared to \$1.3 million for the three months ended June 30, 2020. The decrease of \$1.1 million was due to lower investment yields on our marketable securities.

#### Comparison of the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,			Dollar	
		2021	2021 2020		Change
			(In	thousands)	
Collaboration revenue	\$	10,678	\$	10,341	\$ 337
Operating expenses:					
Research and development		93,551		68,667	24,884
General and administrative		25,087		30,341	(5,254)
Total operating expenses		118,638		99,008	19,630
Loss from operations		(107,960)		(88,667)	(19,293)
Other income, net		642		3,322	(2,680)
Net loss	\$	(107,318)	\$	(85,345)	\$ (21,973)

#### Revenue

Collaboration revenue was \$10.7 million for the six months ended June 30, 2021, compared to \$10.3 million for the six months ended June 30, 2020. We recognize revenue from the upfront payments under the AbbVie Agreement over time as the services are provided. Revenues are recognized as the program costs are incurred by measuring actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Changes in estimates for revenue recognized over time are recognized on a cumulative basis. Revenue increased by \$0.3 million primarily due to an increase in total expected costs for the AL002 program compared to the same period last year.

### Research and Development Expenses

Research and development expenses were \$93.6 million for the six months ended June 30, 2021, compared to \$68.7 million for the six months ended June 30, 2020. The increase of \$24.9 million was driven by a \$8.8 million increase in personnel-related expenses, including stock-based compensation, due to an increase in headcount and issuance of equity grants to employees. Expenses increased by \$7.9 million for other early stage programs as we continue to invest in developing our pipeline. In addition, \$6.8 million increase in AL002 related to clinical costs related to continued progression through clinical trials.

	June 30,				Dollar
	 2021		2020		Change
	_	(In	thousands)		
Direct research and development expenses					
AL001	\$ 17,687	\$	16,048	\$	1,639
AL101	2,041		2,543		(502)
AL002	14,711		7,923		6,788
AL003	2,788		4,707		(1,919)
AL044	4,256		5,060		(804)
Other early stage programs	16,190		8,315		7,875
Indirect research and development expenses					
Personnel related (including stock-based					
compensation)	27,196		18,430		8,766
Facilities and other unallocated research and					
development expenses	 8,682		5,641		3,041
Total research and development expenses	\$ 93,551	\$	68,667	\$	24,884

Six Months Ended

#### General and Administrative Expenses

General and administrative expenses were \$25.1 million for the six months ended June 30, 2021, compared to \$30.3 million for the six months ended June 30, 2020. The decrease of \$5.3 million was driven by a \$7.2 million decrease in legal expense due to arbitration costs ending in 2020. This was offset by an increase of \$2.1 million in personnel-related expenses, including stock-based compensation, due to an increase in headcount and issuance of equity grants to employees.

#### Other Income, Net

Other income, net was \$0.6 million for the six months ended June 30, 2021, compared to \$3.3 million for the six months ended June 30, 2020. The decrease of \$2.7 million was due lower investment yields on our marketable securities.

#### **Liquidity and Capital Resources**

Since our inception through June 30, 2021, our operations have been financed primarily by sales of our convertible preferred stock, upfront payments from the AbbVie Agreement, and proceeds from our IPO and follow-on offering.

As of June 30, 2021, we had \$319.6 million of cash, cash equivalents, and marketable securities. As of June 30, 2021, we had an accumulated deficit of \$517.4 million.

#### **Future Funding Requirements**

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs, and to a lesser extent, general and administrative expenditures. We expect our expenses to continue to increase in connection with our ongoing activities, in particular as we continue to advance our product candidates and our discovery programs. In addition, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities, combined with the anticipated net proceeds expected from the GSK collaboration beginning in the third quarter of 2021, will enable us to fund our operating expenses and capital expenditure requirements into mid-2024. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We may also choose to seek additional financing opportunistically. We expect to need to obtain substantial additional funding in the future for our research and development activities and continuing operations. If we were unable to raise capital when needed or on favorable terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

Our f	future capital requirements will depend on many factors, including:
	the timing and progress of preclinical and clinical development activities; including, without limitation, our collaboration efforts with GSK and AbbVie;
	the number and scope of preclinical and clinical programs we decide to pursue;

Ш	successful enformment in and completion of chinical trials,
	our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if our product candidates are approved, commercial manufacturing;
	our ability to maintain our current research and development programs and establish new research and development programs;
	addition and retention of key research and development personnel;
	our efforts to enhance operational, financial, and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
	negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
	the timing and amount of milestone and other payments we may receive under our collaboration arrangements;
	our eventual commercialization plans for our product candidates;
	the costs involved in prosecuting, defending, and enforcing patent claims and other intellectual property claims; and
П	the costs and timing of regulatory approvals

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

#### Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

		Six Months Ended June 30,		
		2021		2020
Cash used in operating activities	\$	(97,236)	\$	(78,255)
Cash provided by (used in) investing activities		166,144		(149,616)
Cash provided by financing activities		6,836		230,731

#### **Operating Activities**

For the six months ended June 30, 2021, cash used in operating activities was \$97.2 million. This was mainly due to the net loss of \$107.3 million and the decrease in deferred revenue of \$10.7 million as revenue was recognized related to the AbbVie Agreement. We also had a decrease of \$4.2 million in accrued liabilities and accrued clinical supply costs. This was offset by non-cash charges of \$17.9 million for stock-based compensation, \$3.1 million for depreciation and amortization, and a \$9.1 million increase in accounts payable.

For the six months ended June 30, 2020, cash used in operating activities was \$78.3 million. This was mainly due to the net loss of \$85.3 million and the decrease in deferred revenue of \$10.3 million as revenue was recognized related to the AbbVie Agreement. This was offset by a non-cash charge of \$13.6 million for stock-based compensation and an increase of \$5.8 million in accrued liabilities and accrued clinical supply costs.

#### **Investing Activities**

For the six months ended June 30, 2021, cash provided in investing activities of \$166.1 million was primarily related to the maturities of marketable securities of \$173.0 million offset by purchases of marketable securities of \$5.1 million.

For the six months ended June 30, 2020, cash used in investing activities of \$149.6 million was primarily related to the purchase of short-term marketable securities of \$307.4 million offset by the proceeds from maturities of marketable securities of \$161.6 million. In addition, we used cash for the purchase of \$3.9 million of property and equipment.

#### **Financing Activities**

For the six months ended June 30, 2021, cash provided by financing activities of \$6.8 million was primarily from the exercise of options to purchase common stock.

For the six months ended June 30, 2020, cash provided by financing activities of \$230.7 million was primarily from \$224.6 million net proceeds of the issuance of 9,602,500 shares of our common stock upon the completion of a follow-on public offering. In addition, we received \$5.4 million cash from exercise of options to purchase common stock.

#### **Critical Accounting Polices and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Other than the disclosures below, there have been no material changes to our critical accounting policies and estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K, as filed with the SEC on February 25, 2021.

#### Revenue Recognition

We recognize collaboration revenue by measuring the progress toward complete satisfaction of the performance obligation using an input measure. In order to recognize revenue over the research and development period, the Company measures actual costs incurred to date compared to the overall total expected costs to satisfy the performance obligation. Revenues are recognized as the program costs are incurred. We re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. Clinical trials are expensive and can take many years to complete, and the outcome is inherently uncertain. Changes in our forecasted costs are likely to occur over time based upon changes in clinical trial procedures set forth in protocols, changes in estimates of manufacturing costs, or feedback from regulators on the design or operation of our clinical trials. We have had changes to the overall expected costs to satisfy the performance obligations from period to period. For the three months ended June 30, 2021, we had a 1% increase in the forecast of the total expected costs. For the three months ended June 30, 2021, the increase in the overall expected costs to satisfy the performance obligation resulted in an approximately \$0.7 million reduction in revenue compared to if the expected costs had remained the same, as a result of the cumulative catch up for the change in estimate. Collaboration revenue under our collaboration agreement with AbbVie during the three and six months ended June 30, 2021 was \$6.8 million and \$10.7 million, respectively, the entire amount of which was included in deferred revenue at the beginning of the period. The balance of deferred revenue was \$121.6 million as of June 30, 2021. The deferred revenue is expected to be recognized over the research and development period of the programs through the completion of Phase 2 clinical trials.

## Stock-based Compensation

Stock-based compensation is measured at the date of grant, based on the estimated fair value of the award and recognized as expense over the employee's requisite service period (usually the vesting period). We estimate the grant date fair value of options, and the resulting stock-based compensation, using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

*Expected Term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term was derived by using the simplified method which uses the midpoint between the average vesting term and the contractual expiration period of the stock-based award.

Expected Volatility—We have limited information on the volatility of our stock as shares of our common stock were not actively traded on any public markets prior to February 7, 2019. The expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry. These companies are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards. In 2020, we began giving weight to our own historical volatility in the determination of expected volatility.

*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the measurement date with maturities approximately equal to the expected term.

*Expected Dividend*—The expected dividend rate is zero because we have not historically paid and do not expect for the foreseeable future to pay a dividend on our common stock.

Stock-based compensation associated with RSUs is based on the fair value of the Company's common stock on the grant date, which equals the closing price of the Company's common stock on the grant date. The Company recognizes expense over the vesting period of the awards. Expense for options and RSUs are recognized on a straight-line basis.

The Company also granted RSUs with market conditions to certain executives. The fair value of the RSUs with market conditions are estimated using a Monte Carlo simulation model. Assumptions and estimates utilized in the model include the stock price on grant date, risk-free interest rate, dividend yield, expected stock volatility, and the estimated period to achieve the market condition. The expense is recognized based on continued employment of the participants, regardless of achievement of the market condition. Expense related to the RSUs with market conditions is recognized using the accelerated attribution method. The Company accounts for forfeitures as they occur for all awards.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

#### **Interest Rate Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and generally short-term duration, invested in compliance with our policy.

We had cash, cash equivalents, and marketable securities of \$319.6 million as of June 30, 2021, which consisted primarily of bank deposits, money market funds, government marketable securities, and corporate bonds. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. Due to the generally short-term maturities of our cash equivalents and marketable securities, and the low risk profile of our marketable securities, an immediate 100 basis point increase or decrease in interest rates would cause a change in fair value of approximately \$1.0 million.

#### Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. However, we have entered into a limited number of contracts with vendors for research and development services with payments denominated in foreign currencies, including the Euro. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

#### Item 4. Controls and Procedures.

# **Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

As of June 30, 2021, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, performed an evaluation 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) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and the Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of June 30, 2021, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

# **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II—OTHER INFORMATION

#### Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation, or other legal proceedings can have an adverse impact on us because of legal fees and settlement costs, diversion of management resources, and other factors.

#### Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

#### **Summary Risk Factors**

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company, as fully described below. The principal factors and uncertainties that make investing in our company risky include, among others:

We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.
We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.
Drug development is a highly uncertain undertaking and involves a substantial degree of risk.
We will need to obtain substantial additional financing to complete the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our commercialization efforts, product development, or other operations.
Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on programs that do not yield a successful product candidate or fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
Research and development of biopharmaceutical products is inherently risky, and our business is heavily dependent on the successful development of our product candidates, which are in the early stages of preclinical and clinical development, so we cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.
We may not be successful in our efforts to continue to create a pipeline of product candidates from our Discovery Platform or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates from our Discovery Platform, our commercial opportunity may be limited.
We may not be successful in the collaborations for our product development and research programs; for instance, without limitation, failure to complete in a timely manner or at all the proposed transaction with Glaxo Wellcome UK Limited, a subsidiary of GlaxoSmithKline plc (GSK);
We may not be successful in our efforts to expand indications for approved product candidates.
23

We have concentrated a substantial portion of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development. Further, our product candidates are based on new approaches and novel technology, and we must be able to identify and develop new biomarkers that are signs of a disease or condition and that can measure impact on disease progression of our product candidates, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.
We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
Our clinical trials may reveal significant adverse events, toxicities, or other side effects and may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.
We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
Our operations and financial results could continue to be adversely impacted by the COVID-19 pandemic in the United States and the rest of the world.
The market price of our common stock may continue to be volatile, which could result in substantial losses for investors.

#### Risks Related to Our Business, Financial Condition, and Capital Requirements

We are in the early stages of clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability.

We are a clinical stage biopharmaceutical company with a limited operating history, focused initially on developing therapeutics for neurodegenerative diseases, including FTD, Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis (ALS). We commenced operations in May 2013. To date, we have only generated revenue from our collaboration arrangements and a government grant. We have no products approved for commercial sale and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We are in Phase 2 and Phase 3 clinical trials for one product candidate, AL001, are in Phase 2 clinical trials for one product candidate, AL002, and are in Phase 1 clinical trials for two product candidates, AL003 and AL101. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty.

We will encounter risks and difficulties frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We have incurred net losses in each reporting period since our inception, including net losses of \$55.1 million and \$107.3 million for the three and six months ended June 30, 2021, respectively. We have incurred net losses of \$45.3 million and \$85.3 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$517.4 million.

We have invested significant financial resources in research and development activities, including for our preclinical and clinical product candidates. We do not expect to generate revenue from product sales for several years, if at all. The revenue we currently generate from our collaboration arrangement with AbbVie Biotechnology, Ltd. (AbbVie) is variable and limited in amount. For our collaboration with AbbVie, we recognize collaboration revenue by measuring the progress towards complete satisfaction of the performance of obligation measured as the program costs are incurred. The amount of our future net losses will depend, in part, on the level of our future expenditures and revenue. Moreover, our net losses 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.

On July 1, 2021, we entered into an agreement with GSK (GSK Agreement) to collaborate on the global development and commercialization of progranulin-elevating monoclonal antibodies, AL001 and AL101. Under the terms of the GSK Agreement, Alector will receive \$700 million in upfront payments, \$500 million expected to be paid in the third quarter of 2021 and \$200 million expected to be paid in the first quarter of 2022. In addition, based on the development and commercialization plan for AL001 and AL101, Alector will be eligible to receive up to an additional \$1.5 billion in clinical development, regulatory, and commercial launch-related milestone payments.

Developing our product candidates is expensive, and we expect to continue to spend substantial amounts as we fund our early-stage research projects and continue to advance our programs through preclinical and clinical development. Even if we are successful in developing our product candidates, obtaining regulatory approvals and launching and commercializing any product candidate will require substantial additional funding.

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

continue our research and discovery activities;
advance our Discovery Platform, including our target, patient, and biomarker selections;
progress our current and any future product candidates through preclinical and clinical development;
initiate and conduct additional preclinical, clinical, or other studies for our product candidates;
work with our contract development and manufacturing organizations (CDMOs) to scale up the manufacturing processes for our product candidates or, in the future, establish and operate a manufacturing facility;
change or add additional contract manufacturers or suppliers;
seek regulatory approvals and marketing authorizations for our product candidates;
establish sales, marketing, and distribution infrastructure to commercialize any products for which we obtain approval;
make milestone, royalty, or other payments due under any license or collaboration agreements;
take steps to seek protection of our intellectual property and defend our intellectual property against challenges from third parties;
obtain, maintain, protect, and enforce our intellectual property portfolio, including intellectual property obtained through license or collaboration agreements;
attract, hire, and retain qualified personnel;
provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future;
experience any delays or encounter other issues related to our operations, including due to the COVID-19 pandemic;
implement additional internal systems and infrastructure related to cybersecurity;
meet the requirements and demands of being a public company; and
defend against any product liability claims or other lawsuits related to our products.

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

#### Drug development is a highly uncertain undertaking and involves a substantial degree of risk.

We have no products approved for commercial sale. To obtain revenues from the sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing,

profitability d	epends on many factors, including:
	completing research and preclinical and clinical development of our product candidates;
	addressing any delays in our clinical trials or other impacts resulting from factors related to the COVID-19 pandemic;
	obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development and clinical trials;
	developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand of our product candidates;
	identifying, assessing, acquiring, and/or developing new product candidates;
	negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
	launching and successfully commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing, and distribution infrastructure;
	obtaining and maintaining an adequate price for our product candidates, both in the United States and in foreign countries where our products are commercialized;
	obtaining adequate reimbursement for our product candidates from payors;
	obtaining market acceptance of our product candidates as viable treatment options;
	addressing any competing technological and market developments;
	receiving milestones and other payments under our current and any future collaboration arrangements;
	maintaining, protecting, expanding, and enforcing our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
	attracting, hiring, and retaining qualified personnel.
ъ	

obtaining regulatory approval for, manufacturing, and marketing therapies with significant commercial success. Our ability to generate revenue and achieve

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by the U.S. Food and Drug Administration (FDA) or foreign regulatory agencies, to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved product candidate and ongoing compliance efforts.

We will need to obtain substantial additional financing to complete the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our commercialization efforts, product development, or other operations.

Our operations have required substantial amounts of cash since inception, and we expect our expenses to increase significantly in the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities and upfront payments received in connection with our collaboration arrangement with AbbVie. On July 1, 2021, we entered into an agreement with GSK to collaborate on the global development and commercialization of progranulin-elevating monoclonal antibodies, AL001 and AL101. The GSK Agreement is subject to the satisfaction of customary closing conditions. Developing our product candidates and conducting clinical trials for the treatment of neurodegenerative diseases, including FTD, Alzheimer's disease, and Parkinson's disease, will require substantial amounts of capital. We will also require a significant amount of capital for the further development of our product candidates, and if any of such product candidates are approved, to commercialize any approved products.

As of June 30, 2021, we had cash, cash equivalents, and marketable securities of \$319.6 million. In January 2020, we received \$224.5 million of net proceeds from the issuance of common stock upon the completion of a follow-on offering, net of underwriting discounts and commissions and offering expenses. In May 2020, we established an "at-the-market" facility

for the sale of up to \$150 million worth of shares of common stock from time to time by entering into an equity distribution agreement with Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC, as sales agents. We have not issued any shares pursuant to any at-the-market offerings but may at a future date.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities, combined with the anticipated net proceeds expected from the GSK collaboration beginning in the third quarter of 2021, will be sufficient to fund our projected operations into mid-2024. Our estimate as to how long we expect our existing cash, cash equivalents, and marketable securities to be available to fund our operations is based on assumptions that may be proved inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

Global markets have experienced volatility in connection with continued concerns over the global impact of COVID-19 and subsequent variants. Our ability to raise money in the public markets may be severely impacted for the foreseeable future due to the COVID-19 pandemic. Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back, or discontinue our research and development programs or the commercialization of any product candidates, if approved, or be unable to continue or expand our operations, or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations, and growth prospects and cause the price of our common stock to decline.

To the extent that we raise additional capital through the sale of 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 your rights as a common stockholder. 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 collaborations, strategic alliances, or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or grant licenses on terms that may not be favorable to us.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on programs that do not yield a successful product candidate or fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have identified over 100 immune system targets, have advanced four product candidates, AL001, AL002, AL003, and AL101 into clinical development, and continue to develop our research pipeline. We currently have four product candidates in clinical trials. Together, the development of these programs and product candidates require significant capital investment. Due to the significant resources required for the development of our programs and product candidates, we must focus our programs and product candidates on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our drug development strategy is to clinically test and seek regulatory approval for our product candidates in indications in which we believe there is the most evidence that we will be able to quickly generate proof-of-concept data. We then intend to expand to clinical testing and seek regulatory approvals in other neurodegenerative indications based on genetic and mechanistic overlap with the primary indication.

However, even if our product candidates are able to gain regulatory approval in one indication, there is no guarantee that we will be able to expand to other indications, and we may expend significant resources in seeking such approvals. In addition, we may focus resources on pursuing indications outside of neurodegeneration based on the same genetic and mechanistic rationale we utilize in determining on which of our discovery programs to focus. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate, or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the biopharmaceutical industry, in particular for neurodegenerative diseases, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other

royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

#### Risks Related to the Discovery, Development, and Commercialization of Our Product Candidates

Research and development of biopharmaceutical products is inherently risky. Our business is heavily dependent on the successful development of our product candidates, which are in various stages of preclinical and clinical development. We cannot give any assurance that any of our product candidates will receive regulatory, including marketing, approval, which is necessary before they can be commercialized.

We are at the early stages of development of many of the product candidates currently in our programs. To date, we have invested substantially in our efforts and financial resources to identify, procure intellectual property for, and develop our programs, including conducting preclinical studies and clinical trials in our programs for our product candidates, AL001, AL002, AL003, AL101, AL044, and AL009, and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

L	our product candidates may not successfully complete preclinical studies or clinical trials;
	a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
	our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
	the product candidates that we develop may not be sufficiently covered by intellectual property for which we hold exclusive rights;
	the product candidates that we develop may be covered by third parties' patents or other intellectual property or exclusive rights;
	the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
	a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
	if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and
Г	a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may not be successful in our efforts to further develop our current product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Most of our product candidates are in the early stages of development and will require significant additional clinical development, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all.

We have never completed a clinical development program. We currently have one product candidate, AL001, in a pivotal Phase 3 clinical trial, one product candidate, AL002 in a Phase 2 clinical trial, and two product candidates, AL003 and AL101, in Phase 1 clinical trials. Further, we cannot be certain that any of our product candidates will be successful in clinical trials. We may in the future advance product candidates into clinical trials and terminate such trials prior to their completion.

If any of our product candidates successfully complete clinical trials, we generally plan to seek regulatory approval to market our product candidates in the United States, the European Union, and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled, or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, manufacturing and controls, clinical trials, commercial sales,

pricing, and distribution of our product candidates. We may also rely on our collaborators or partners to conduct the required activities to support an application for regulatory approval, and to seek approval, for one or more of our product candidates. For example, for our AL002 and AL003 product candidates, our collaboration arrangement with AbbVie provides that we are responsible for the execution of the Phase 1 and Phase 2 studies. We cannot be sure that our collaborators or partners will conduct these activities or do so within the timeframe we desire. Even if we (or our collaborators or partners) are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our business, financial condition, results of operations, and our growth prospects could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, whether for the treatment of neurodegenerative diseases or other diseases, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates.

We may not be successful in our efforts to continue to create a pipeline of product candidates from our Discovery Platform or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates from our Discovery Platform, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional product candidates. Identifying, developing, obtaining regulatory approval, and commercializing additional product candidates for the treatment of neurodegenerative diseases will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop, or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop, and commercialize additional product candidates, our commercial opportunity may be limited.

#### We may not be successful in our efforts to expand indications for approved product candidates.

Our drug development strategy is to clinically test and seek regulatory approval for our product candidates in indications in which we believe there is the most evidence that we will be able to quickly generate proof-of-concept data. We then intend to expand to clinical testing and seek regulatory approvals in other neurodegenerative indications based on genetic and mechanistic overlap with the primary indication. Conducting clinical trials for additional indications for our product candidates requires substantial technical, financial, and human resources and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be successful in our effort to obtain regulatory approval for our product candidates for additional indications even if we obtain approval for an initial indication.

For example, our product candidate AL001 is initially targeting FTD-*GRN* patients. In the third quarter of 2019, we advanced AL001 into a Phase 2 trial, which also includes an additional genetic subset of FTD patients (FTD-*C9orf72*) and we will evaluate AL001 in patients with ALS caused by *C9orf72* repeats, which share TDP-43 pathology with FTD-*GRN*. If we are unable to expand indications for our product candidates, our commercial opportunity may be limited.

We have concentrated a substantial portion of our research and development efforts on the treatment of neurodegenerative diseases, a field that has seen limited success in drug development. Further, our product candidates are based on new approaches and novel technology, and we must be able to identify and develop new biomarkers that are signs of a disease or condition and that can measure impact on disease progression of our product candidates, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.

We have focused a substantial portion of our research and development efforts on addressing neurodegenerative diseases. Collectively, efforts by biopharmaceutical companies in the field of neurodegenerative diseases have seen limited success in drug development. There are few effective therapeutic options available for patients with FTD, Alzheimer's disease, Parkinson's disease, and other neurodegenerative diseases. Our future success is highly dependent on the successful development of our product candidates for treating neurodegenerative diseases. Developing and, if approved, commercializing our product candidates for treatment of neurodegenerative diseases subjects us to a number of challenges,

including obtaining disease modifying activity and efficacious dose in target tissue and obtaining regulatory approval from the FDA and other regulatory authorities who have only a limited set of precedents to rely on.

Our approach to the treatment of neurodegenerative diseases aims to identify and select targets enriched in microglia and other myeloid immune cells which are genetically associated with neurodegenerative diseases. We identify and develop product candidates that are designed to cross the blood brain barrier in sufficient quantity and potency to enable efficacious dosing in the brain and engage the intended target, and we must be able to identify and develop biomarkers and biomarker assays that can accurately identify signs of a disease or condition, assist us in selecting the right patient population, and demonstrate target engagement, pathway engagement, and measure the impact on disease progression of our product candidates. This strategy may not prove to be successful. We cannot be sure that our approach will yield satisfactory therapeutic products that are safe and effective, scalable, or profitable.

We may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an investigational new drug application (IND) or a clinical trial application (CTA) will result in the FDA or European Medicines Agency (EMA), as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include:

inabi trials	lity to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical;	
	s in confirming target engagement, patient selection, or other relevant biomarkers to be utilized in preclinical and clinical product date development;	
delay	s in reaching a consensus with regulatory agencies on study design;	
,	s in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites, the terms nich can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;	
delays in identifying, recruiting, and training suitable clinical investigators;		
delay	s in obtaining required Institutional Review Board (IRB) approval at each clinical trial site;	
imposition of delays to clinical trials, including as a result of temporary or permanent clinical hold by regulatory agencies for a number of reasons, including:		
	after review of an IND or amendment, CTA or amendment, or equivalent application or amendment;	
	as a result of a new safety finding that presents unreasonable risk to clinical trial participants;	
	as a result of modifications to clinical trial protocols or related documentation;	
	a negative finding from an inspection of our clinical trial operations or study sites; or	
	the finding that the investigational protocol or plan is clearly deficient to meet its stated objectives;	
	s in identifying, recruiting, and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing clinical trials, or failing to return for post-treatment follow-up;	
diffic	rulty collaborating with patient groups and investigators;	
failur	re by our CROs, other third parties, or us to adhere to clinical trial requirements;	
	re to perform in accordance with the FDA's or any other regulatory authority's current good clinical practices (cGCPs) requirements, or cable EMA or other regulatory guidelines in other countries;	
occui	rence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;	
chang	ges in regulatory requirements and guidance that require amending or submitting new clinical protocols;	

	changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
	the cost of clinical trials of our product candidates being greater than we anticipate;
	clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and
	delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use is clinical trials or the inability to do any of the foregoing.
Any ai	nd all of the events described above may be caused or exacerbated by factors related to the ongoing COVID-19 pandemic.
addition, if we to bridge our protection and	ability to successfully initiate or complete clinical trials could result in additional costs to us or impair our ability to generate revenue. In a make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent d may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our dates and may harm our business and results of operations.
EMA, or any their clinical if failure to con- by the FDA, I	ald also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of nvestigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including duct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to a benefit from using a product candidate, changes in governmental regulations or administrative actions, or lack of adequate funding to clinical trial.
We ma	y in the future advance product candidates into clinical trials and terminate such trials prior to their completion, which could adversely affect
approval proc	in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and ess and delay, or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product
We may enco adversely affe	unter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise acted.
	nely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number to remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons,
	the size and nature of the patient population;
	the patient eligibility criteria defined in the protocol, including biomarker-driven identification and/or certain highly-specific criteria related to stage of disease progression, which may limit the patient populations eligible for our clinical trials to a greater extent than competing clinical trials for the same indication that do not have biomarker-driven patient eligibility criteria;
	the size of the study population required for analysis of the trial's primary endpoints;
	the proximity of patients to a trial site;
	the design of the trial;
	our ability to recruit clinical trial investigators with the appropriate competencies and experience;
	delays in enrolling patients in our clinical trials related to the COVID-19 pandemic;
	competing clinical trials for similar therapies or targeting patient populations meeting our patient eligibility criteria;

	clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies and product candidates;
	our ability to obtain and maintain patient consents; and
П	the risk that nationts enrolled in clinical trials will not complete such trials or that we may not be able to collect data from such nationts or

Enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trials have been, and may continue to be, delayed or limited as certain of our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. In addition, patients may not be able or willing to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. These factors resulting from the COVID-19 pandemic could delay or prevent the anticipated readouts from our clinical trials.

that we may not be able to collect data from such patients, for any reason.

Our clinical trials may reveal significant adverse events, toxicities, or other side effects and may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. For those product candidates that are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical trial protocols and the rate of dropout among clinical trial participants. Open-label extension studies may also extend the timing and cost of a clinical test substantially. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in neurodegenerative diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

#### Our operations and financial results could be adversely impacted by the COVID-19 pandemic in the United States and the rest of the world.

The COVID-19 virus and subsequent variants continue to spread throughout the world and adversely impact global commercial activity and contribute to significant volatility in financial markets. The COVID-19 pandemic and government responses are creating disruption in global supply chains and adversely impacting many industries. The pandemic could have

a continued material adverse impact on economic and market conditions and lead to a further extended period of global economic slowdown. We continue to monitor the impact of the COVID-19 pandemic closely. The extent to which the COVID-19 pandemic will impact our operations or financial results is uncertain.

The continuation of the pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as issues including worker shortages, supply chain disruptions, facilities and production suspensions, and spikes in demand for certain goods and services, such as medical services and supplies, persist. In response to the continued spread of COVID-19, we have reduced the number of employees operating at our headquarters, which has altered our operations and processes. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material adverse effect on our business, financial condition and results of operations. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business and clinical trials, including:

the size and nature of the patient population;
delays or difficulties in recruiting, enrolling, and maintaining patients in our clinical trials;
delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
limitations in resources that would otherwise be focused on the conduct of our business or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed "shelter in place" or similar working restrictions;
delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs;
delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

We may be required to develop, implement, and maintain additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus, which may delay our anticipated timelines for clinical studies and regulatory approval and increase our costs for clinical studies. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, that describes a number of considerations for sponsors of clinical trials impacted by the pandemic. In this guidance, pharmaceutical companies would be required to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic related study disruption (by unique subject identifier and by investigational site and a description of how the individual's participation was altered); and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, the FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug and biological products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs and a guidance on resuming normal drug and biologics manufacturing operations during the COVID-19 public health crisis. Other COVID-19 industry guidance recently issued by the FDA address remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities; and manufacturing, supply chain, and drug and biological product inspections, among others. In view of the continued spread of the COVID-19 variants, FDA may issue additional

and regulations can increase our compliance costs or delay our clinical plans. To the extent our clinical studies are delayed or data from our clinical studies become compromised due to COVID-19 related factors, we may be required to expend additional resources to conduct additional studies and/or enroll more participants, which could adversely affect our business operations and delay regulatory approval.

The COVID-19 pandemic continues to evolve, with the status of operations and government restrictions evolving weekly. The extent to which the outbreak impacts our business, preclinical studies, and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions, social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We may also suffer from any of the foregoing disruptions as the COVID-19 virus and subsequent variants continue to develop and experience a resurgence in any particular country or region in the future.

Additionally, certain third parties with whom we engage, including our collaborators, contract organizations, third party manufacturers, suppliers, clinical trial sites, regulators and other third parties with whom we conduct business are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties experience shutdowns or continued business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

For example, certain of our clinical trial sites have experienced clinical trial visit delays, and we are aware that for a period of time, some participants in each of our ongoing trials did not receive scheduled doses on time. These events could negatively impact the integrity, reliability, or robustness of the data from our clinical trials. We and our CROs have made certain adjustments to the operation of such trials in an effort to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic in accordance with the guidance issued by the FDA, and we may be required to make further adjustments in the future. Many of these adjustments are new and untested, may not be effective, and may have unforeseen effects on the enrollment, progress and completion of these trials and the findings from these trials. In addition, notwithstanding any adjustments, some trial participants may decline to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. We may not be successful in adding clinical trial sites, may experience delays in patient enrollment or in the progression of our clinical trials and collection and analysis of patient data, may need to suspend or abandon our clinical trials, and may encounter other negative impacts to our trials, due to the effects of the COVID-19 pandemic.

The global outbreak of COVID-19 continues to evolve. While the extent of the impact of the current COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results. To the extent the COVID-19 pandemic adversely affects our operations and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced, or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. Moreover, the neurodegenerative field is characterized by strong and increasing competition, and a strong emphasis on intellectual property. We may face competition with respect to any of our product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of products for the treatment of neurodegenerative diseases, including FTD and Alzheimer's disease. Many of these current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring

technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of neurodegenerative disease indications, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, EMA, or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan drug exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity, and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate, or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

The manufacture of our product candidates is complex, and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our drug and biological product candidates are complex, expensive, highly-regulated, and subject to multiple risks. Further, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them in large quantities. Our CDMOs may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our CDMOs are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risk would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design, and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA, and foreign regulatory authority approval processes, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA, and foreign regulatory authority requirements, including complying with current good manufacturing practices (cGMPs) on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA, or other regulatory authorities, including recent FDA guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug and biological products manufacturing, as well as any future guidance and regulations, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CDMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing

responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize any approved product on our own include: our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel; the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors; the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population; the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and unforeseen costs and expenses associated with creating an independent commercialization organization. If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved. Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success. The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Even if any product candidates we may develop receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including: the efficacy and safety of such product candidates as demonstrated in clinical trials and published in peer-reviewed journals; П П the potential and perceived advantages compared to alternative treatments; the ability to offer our products for sale at competitive prices; sufficient third-party coverage or reimbursement; П the ability to offer appropriate patient access programs, such as co-pay assistance; П the extent to which physicians recommend our products to their patients;

convenience and ease of dosing and administration compared to alternative treatments;

Ш	the clinical indications for which the product candidate is approved by FDA, EMA, or other regulatory agencies;
	product labeling or product insert requirements of the FDA, EMA, or other comparable foreign regulatory authorities, including any limitations, contraindications, or warnings contained in a product's approved labeling;
	restrictions on how the product is distributed;
	the timing of market introduction of competitive products;
	publicity concerning our products or competing products and treatments;
	the strength of marketing and distribution support; and
	the prevalence and severity of any side effects.

If any product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenue, and we may not become profitable.

Any products we commercialize may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted or potential future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid, and Veterans Affairs hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to get reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA, EMA, or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels

already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

### Our product candidates for which we intend to seek approval may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these product candidates pursuant to the Biologics License Application (BLA) pathway. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get it on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

#### Any legal proceedings or claims against us could be costly and time-consuming to defend and could harm our reputation regardless of the outcome.

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, including intellectual property, data privacy, product liability, employment, class action, whistleblower and other litigation claims, and governmental and other regulatory investigations and proceedings. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability, or require us to change our business practices. In addition, the expense of litigation and the timing of this expense from period to period are difficult to estimate, subject to change, and could adversely affect our financial condition and results of operations. Because of the potential risks, expenses, and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Any of the foregoing could adversely affect our business, financial condition, and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk when and if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. 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, or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

	decreased or interrupted demand for our products;
	injury to our reputation;
	withdrawal of clinical trial participants and inability to continue clinical trials;
	initiation of investigations by regulators;
	costs to defend the related litigation;
	a diversion of management's time and our resources;
	substantial monetary awards to trial participants or patients;
	product recalls, withdrawals or labeling, marketing, or promotional restrictions;
	loss of revenue;
	exhaustion of any available insurance and our capital resources; and
П	the inability to commercialize any product candidate.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

### Risks Related to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA, EMA, and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA, and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, the U.S. federal government has experienced and may in the future experience shutdown or budget sequestration, which could result in significant reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. To the extent FDA and other regulatory authorities

experience any delays or limited resources in reviewing our regulatory applications or requests for meetings and/or guidance, and inspection of manufacturing facilities prior to regulatory approval due to the COVID-19 pandemic or other reasons, we may experience significant delays in our anticipated timelines for our clinical studies and/or seeking regulatory approvals, which could adversely affect our business.

Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following: the FDA, EMA, or comparable foreign regulatory authorities may disagree with the design, implementation, or the interpretation of the results of our clinical trials; the FDA, EMA, or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application (NDA), BLA, or other submission or to obtain regulatory approval in the United States or elsewhere; we may be unable to demonstrate to the FDA, EMA, or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for a proposed indication, when compared to the standard of care, is acceptable; the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory

approval, limit their commercial potential, or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA, or other comparable foreign regulatory authorities.

Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, and/or result in potential product liability claims. We are required to maintain product liability insurance pursuant to certain of our development and commercialization agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations, business, and reputation. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

regulatory authorities may withdraw approvals of such product and cause us to recall our products;
regulatory authorities may require additional warnings on the label;
40

	we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
	we may be required to create a Risk Evaluation and Mitigation Strategy 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, such as boxed warning on the packaging, 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 the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations, and growth prospects.

We currently are and may continue in the future to conduct clinical trials for our product candidates outside the United States, and the FDA, EMA, and applicable foreign regulatory authorities may not accept data from such trials.

We currently are and may continue in the future choose to conduct one or more of our clinical trials outside the United States, including in Europe or Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to cGCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

### Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA, EMA, and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, BLA, or marketing authorization application (MAA). Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a Risk Evaluation and Mitigation Strategy), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA, and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withd

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, such 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 that would result in adverse publicity;
impose civil or criminal penalties;
suspend or withdraw regulatory approvals;
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;
seize or detain products; or
require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We have received orphan drug designation from the FDA for AL001 and AL101 for treatment of FTD and plan to seek orphan drug designation for some of our other product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States

for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. While we have obtained orphan drug designation from the FDA for AL001 and AL101 for treatment of FTD, we may be unable to reap the benefits associated with orphan drug status. In addition, we plan to seek orphan drug designations for some of our other product candidates in the future but may be unable to obtain an orphan drug designation for any additional product candidates.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other NDA or BLA applications to market the same drug or biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even though the FDA has approved orphan drug status for AL001 and AL101 for treatment of FTD, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We have received Fast Track designation from the FDA for AL001 and AL101 for the treatment of patients with frontotemporal dementia carrying specific genetic mutation in the granulin gene, but we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

Fast Track designation is designed to facilitate the development and expedite the review of therapies which treat serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review, and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product and the specific indication for which it is being studied.

In December 2019, the FDA granted Fast Track designation for AL101 and in January 2020, the FDA granted Fast Track designation for AL101 for the treatment of patients with FTD carrying specific genetic mutations in the granulin gene. If our clinical development program does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended, or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

### Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, or Affordable Care Act (ACA) was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA, including judicial challenges in the Fifth Circuit Court and the United States Supreme Court. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. It is unclear how this Supreme Court decision, future litigation, or healthcare measures promulgated by the Biden administration will impact our business, financial condition, and results of operations.

Complying with any new legislation or changes in healthcare regulation could be time-intensive and expensive, resulting in a material adverse effect on our business.

There have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, HHS and CMS issued final rules in November and December of 2020 that were expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. The Biden administration implemented a regulatory rule freeze for all federal agency rules that had not gone into effect as of January 20, 2021. The impact of these lawsuits as well as legislative, executive, and administrative actions of the Biden administration on us and the pharmaceutical industry as a whole is currently unknown.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

	the demand for our product candidates, if we obtain regulatory approval;
	our ability to receive or set a price that we believe is fair for our products;
	our ability to generate revenue and achieve or maintain profitability;
	the level of taxes that we are required to pay; and
П	the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. Further, the governmental may take further action to address the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. This could lower the price that we receive for any approved product. The Biden administration and the states may pass further legislation and regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability, or commercialize our product candidates, if approved. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:

rs, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to:			
	comply with the laws of the FDA, EMA, and other comparable foreign regulatory authorities;		
	provide true, complete, and accurate information to the FDA, EMA, and other comparable foreign regulatory authorities;		
	comply with manufacturing standards we have established;		
	44		

	comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or
	report financial information or data accurately or to disclose unauthorized activities to us.
under such lav sales, marketin self-dealing, a promotion, sal involve the im serious harm t employees and or losses or in any such actio	btain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure we will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, ng, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and es and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also proper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause of our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by dithird parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If ns are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant business, including the imposition of significant fines or other sanctions.
If we fail to co affected.	omply with healthcare laws, we could face substantial penalties and our business, operations, and financial conditions could be adversely
	btain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be ous federal and state fraud and abuse laws. The laws that may impact our operations include the following:
	The federal Anti-Kickback Statute, prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, 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.
	Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease, or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.
	The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
	HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information without appropriate authorization.
,	45

Ш	The federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include payments and transfers of value made during the previous year to certain non-physician providers, such as physician assistants and nurse practitioners.
	Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
	Analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection, and unfair competition laws may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements, as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers.
	State laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources.
	State laws also require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration, and items of value provided to healthcare professionals and entities.
	State and foreign laws also govern the privacy and security of health information in certain 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, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development, and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain

workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business is subject to complex and evolving U.S. and foreign laws and regulations relating to security, privacy, and data protection. These laws and regulations are subject to change and uncertain interpretation, and could result in claims, changes to our business practices, or monetary penalties, and otherwise may harm our business.

A wide variety of state, national, and international laws and regulations apply to security and cybersecurity requirements and the collection, use, retention, protection, disclosure, transfer, and other processing of personal data. These security and data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions. We are working to comply with these laws, and we anticipate needing to devote significant additional resources to our compliance efforts. It is possible that the new legislation may impose new obligations and requirements on similarly situated companies, and these laws may be interpreted and applied in a manner that is inconsistent from jurisdiction to jurisdiction or inconsistent with our current policies and practices. Our actual or perceived failure to adequately comply with applicable laws and regulations relating to security, privacy, and data protection, or to protect our systems, personal data, and other data we process or maintain, could result in regulatory fines, investigations and enforcement actions, penalties and other liabilities, claims for damages by affected individuals, and damage to our reputation, any of which could materially affect our business, financial condition, results of operations, and prospects.

Inadequate funding for the FDA and other government agencies could hinder our ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In the past, the U.S. government has experienced budgetary shutdowns and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

## Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA.

Recently the Securities and Exchange Commission (SEC) and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our

employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

#### **Risks Related to Our Reliance on Third Parties**

We expect to depend on collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We currently use and expect to continue to use third-party collaborators for the research, development, and commercialization of certain of the product candidates we may develop, including our previously disclosed arrangements with AbbVie and Adimab, LLC (Adimab). We have entered into a licensing agreement with Innovent Biologics to develop and commercialize our AL008 product, an anti-SIRP-alpha antibody for the treatment of oncology indications in China. In July 2021, we entered into the GSK Agreement to collaborate on the global development and commercialization of progranulinelevating monoclonal antibodies, AL001 and AL101. The transaction is contingent on satisfaction of requirements under applicable antitrust laws, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, in the U.S., and other customary closing conditions, and with respect to the collaboration and the execution of a definitive collaboration agreement.

Our likely collaborators for any other collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies, and academic institutions. Such arrangements with any third parties, generally provide us with shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs, or any product candidates we may develop, pose the following risks to us: collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations; collaborators may not properly obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our product candidates or research programs or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property; collaborators may own or co-own intellectual property covering our product candidates or research and development programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or research programs; we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us; collaborators may control certain interactions with regulatory authorities, which may impact our ability to obtain and maintain regulatory approval of our product candidates; disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources; collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities or collaborators may elect to fund or commercialize a competing product;

	collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
	collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
	collaborators may restrict us from researching, developing, or commercializing certain products or technologies without their involvement;
	collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
	we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
	collaborators may grant sublicenses to our technology or product candidates or undergo a change of control, and the sublicensees or new owners may decide to take the collaboration in a direction which is not in our best interest;
	collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how, or intellectual property of the collaborator relating to our products, product candidates, or research programs;
	key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
	collaborations may require us to incur short and long-term expenditures, issue securities that dilute our stockholders, or disrupt our management and business;
	if our collaborators do not satisfy their obligations under our agreements with them, or if they terminate our collaborations with them, we may not be able to develop or commercialize product candidates as planned;
	collaborations may require us to share in development and commercialization costs pursuant to budgets that we do not fully control, and our failure to share in such costs could have a detrimental impact on the collaboration or our ability to share in revenue generated under the collaboration;
	collaborations may be terminated in their entirety or with respect to certain product candidates or technologies and, if so terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or technologies; and
	collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished, or terminated.
⁄a ma	y face significant competition in seeking appropriate collaborations. Pecent business combinations among biotechnology and pharmacoutical

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

We may not realize the benefit of collaborations if we or our collaborator elects not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. In addition, if our agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us

to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section also apply to the activities of our collaborators and any negative impact on our collaborators may adversely affect us.

We expect to rely on third parties to conduct our clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical trials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible, and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors, including with the shipment of any drug supplies, could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

We contract with third parties for the manufacture of materials for our research programs, preclinical studies, clinical trials, and for commercialization of any product candidates that we may develop. This reliance on third parties carries and may increase the risk that we will not have sufficient quantities of such materials, product candidates, or any medicines that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely on CDMOs for the manufacture of our materials for preclinical studies and clinical trials and expect to continue to do so for preclinical studies, clinical trials, and for commercial supply of any product candidates that we may develop. We currently have established relationships with several CDMOs for the manufacturing of our product candidates. We may be unable to establish any further agreements with CDMOs or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on CDMOs entails additional risks, including:

the possible breach of the manufacturing agreement by the third party;
the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and
the inability to produce required volume in a timely manner and to quality standards.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in clinical holds on our trials, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures, or recalls of product candidates or medicines, operating restrictions,

and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future third-party manufacturers could delay clinical development or marketing approval. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs.

Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We depend on third-party suppliers for key raw materials used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could harm our business.

We rely on third-party suppliers for the supply of the raw materials required for the production of our product candidates, and we expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of raw materials involve several risks, including limited control over pricing, availability, quality, and delivery schedules. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We do not have long-term supply agreements, and we purchase our required drug product on a development manufacturing services agreement or purchase order basis. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

### **Risks Related to Our Intellectual Property**

If we are unable to obtain and maintain patent protection for any product candidates we develop, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad relating to our core programs and product candidates, as well as other technologies that are important to our business. Given that the development of many of our product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of many of our product candidates is also at an early stage. For example, we have filed or intend to file patent applications on aspects of our technology and core product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our core programs and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture for protection of such core programs, product candidates, and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent cla

programs and product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

### If any of our patent applications, or those of our collaborators, do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents or those of our collaborators with respect to our product candidates. With respect to both our intellectual property and that of our collaborators related to our product candidates, we cannot predict whether the patent applications we and our collaborators are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we or our collaborators may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our collaborators were the first to make the inventions claimed in any of our or our collaborators' patents or pending patent applications, or that we or our collaborators were the first to file for patent protection of such inventions.

# If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our or our collaborators' pending and future patent applications may not result in patents being issued which protect our product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we or our collaborators license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents to which we or our collaborators have rights may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We or our collaborators may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our or our collaborators' patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our collaborators, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our collaborators' priority of invention or other features of patentability with respect to our or our

collaborators' patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we or our collaborators are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Some of our patents and patent applications may in the future be co-owned with third parties. In addition, collaborators or future licensors may co-own their patents and patent applications with other third parties with whom we do not have a direct relationship. Our rights to certain of these patents and patent applications may be dependent, in part, on inter-institutional or other operating agreements between the joint owners of such patents and patent applications, who are not parties to our license agreements. If our collaborators or future licensors do not have exclusive control of the grant of licenses under any such third-party co-owners' interest in such patents or patent applications or we are otherwise unable to secure such exclusive rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology to the extent such products and technology are not also covered by our intellectual property. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

#### Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of agreements with others.

We are heavily reliant upon option rights to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates and are subject to the terms and conditions of certain collaboration agreements with third parties. For example, in 2014 we entered into the Adimab Collaboration Agreement with Adimab. Under the Adimab Collaboration Agreement, we are developing antibodies discovered by Adimab in our AL001 and AL101 product candidates, and we are developing antibodies optimized by Adimab in our AL002 and AL003 product candidates. Additionally, in October 2017, we entered into the AbbVie Agreement to co-develop and commercialize medicines with AbbVie to treat Alzheimer's disease and other neurodegenerative diseases. In August 2019, we entered into a new Adimab collaboration agreement for development of antibodies for use in future programs. For additional information on the Adimab Collaboration Agreement and the AbbVie Agreement, see the sections titled "Business—Adimab Collaboration Agreements" and "Business—Strategic Alliance with AbbVie" in our Annual Report on Form 10-K, which was filed with the SEC on February 25, 2021. In July 2021, we entered into the GSK Agreement to collaborate on the global development and commercialization of progranulin-elevating monoclonal antibodies, AL001 and AL101.

Our agreements with Adimab, AbbVie, GSK, and other agreements we enter into in the future may not provide exclusive rights to use certain intellectual property and technology retained by the collaborator in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products that utilizes technology retained by such collaborators to the extent such products are not also covered by our intellectual property.

In addition, subject to the terms of any such agreements, we may not have the right to control the preparation, filing, prosecution, and maintenance, and we may not have the right to control the enforcement and defense of certain patents and patent applications retained by the collaborator and provided to us under a limited license. For example, under the Adimab Collaboration Agreements, patent rights relating to improvements to Adimab's background platform technology that are invented in the course of the research under the Adimab Collaboration Agreements are assigned to Adimab. We also have an exclusive option under the Adimab Collaboration Agreements to obtain with respect to a specified number of antibodies directed against such target and discovered or optimized by Adimab, ownership of certain patent rights relating to such antibodies, including certain patent rights. Until we exercise such option, we and Adimab each grant each other a

non-exclusive license to the relevant intellectual property. In addition, the GSK Agreement contains customary terms governing the prosecution and enforcement of intellectual property.

We cannot be certain that patents and patent applications that are controlled by our collaborators will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our collaborators fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the limited rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates that are subject of such licensed rights could be adversely affected, and we may have a reduced ability to prevent competitors from making, using, and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from collaborators, we may still be adversely affected or prejudiced by actions or inactions of our collaborators that took place prior to the date upon which we assumed control over patent prosecution.

Furthermore, our or our collaborators' patents may be subject to a reservation of rights by one or more third parties. For example, we received an award from the National Institute of Health in support of our research into the production and characterization of novel therapeutic antibodies against the neurotrophic factor PGRN degrading receptor Sortilin (SORT1). As a result, the U.S. government may have certain rights to resulting intellectual property. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention or to have others use the invention on its behalf. The U.S. government's rights may also permit it to disclose the funded inventions and technology to third parties and to exercise march-in rights to use or allow third parties to use the technology developed using U.S. government funding. The U.S. government may exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of the government funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in facilities in the United States in certain circumstances and if this requirement is not waived. Any exercise by the U.S. government of such rights or by any third party of its reserved rights could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in the agreements under which we option or license intellectual property rights from our collaborators or future licensors or otherwise experience disruptions to our business relationships with our collaborators or future licensors, we could lose intellectual property rights that are important to our business.

We have entered into agreements with our collaborators to option or license certain intellectual property and may need to obtain additional intellectual property rights from others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain additional intellectual property rights at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In addition, each of our agreements with collaborators do, and we expect our future agreements will, impose various economic, development, diligence, commercialization, and other obligations on us. Certain of our collaboration agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. In spite of our efforts, our collaborators might conclude that we have materially breached our obligations under such agreements and might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. If termination of these agreements causes us to lose the rights to certain patents or other intellectual property, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and growth prospects.

Moreo	ver, disputes may arise regarding intellectual property subject to a collaboration agreement, including:
	the scope of the option or license rights granted under the agreement and other interpretation-related issues;
	54

П	license rights granted under the agreement;
	the sublicensing of patent and other rights under our collaborative development relationships;
	our diligence obligations under the agreement and what activities satisfy those diligence obligations;
	the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
	the priority of invention of patented technology.

In addition, the agreements under which we currently have rights to option or license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Moreover, if disputes over intellectual property that we have optioned or licensed prevent or impair our ability to maintain our current arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and growth prospects.

### We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, our collaborators or any of our future licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our collaborators or licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require

compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We also are dependent on our collaborators or licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

### Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act), the first inventor to file a patent application in the United States is entitled to the patent on an invention regardless of whether another party was the first to invent the claimed invention. Therefore, a third party that files a patent application in the USPTO after March 2013, but before us, could be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This possibility will require us to be cognizant going forward of the time from invention to the time of filing a patent application. Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our product candidates or other technologies.

Certain procedures at the USPTO under the America Invents Act could affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Rulings from the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

## Issued patents covering our product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no

invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and growth prospects.

### If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and growth prospects could be materially harmed.

### We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants, or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, trade secrets, or other intellectual property. If the defense of any such claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We consider trade secrets and know-how to be one of our primary sources of intellectual property. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

## We may not be successful in obtaining, through acquisitions or otherwise, necessary rights to our product candidates or other technologies.

Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of neurodegeneration therapy may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain technologies for use with future product candidates. In addition, with respect to any patents we co-own with third parties, we may wish to obtain licenses to such co-owners' interest to such patents. However, we may be unable to secure such licenses or otherwise acquire any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our future product candidates. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital 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 or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

# We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

# Third-party claims of intellectual property infringement, misappropriation, or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates and other technologies.

The field of discovering treatments for neurodegenerative diseases is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. Additionally, the technology used in our product candidates is still in its infancy and no products utilizing similar technology have yet reached the market. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to develop, manufacture, market, and sell any product candidates that we develop and to use our proprietary technologies without infringing, misappropriating, and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may become party to, or threatened with, such actions in the future, regardless of their merit. As discussed above, recently, due to changes in U.S. law

referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing product candidates, and other technologies might assert are infringed by our current or future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or other technologies may infringe.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates or other technologies infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated, or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

## We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent in which we have an interest is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with

intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

## If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations, and growth prospects.

### Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights	have	limitations	and may
not adequately protect our business or permit us to maintain our competitive advantage. For example:			

others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own;
we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future;
we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
it is possible that our current or future pending owned or licensed patent applications will not lead to issued patents;
issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
we may not develop additional proprietary technologies that are patentable;
the patents of others may harm our business; and
we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

### **Risks Related to Our Operations**

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate, and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management, particularly our Chief Executive Officer, Dr. Arnon Rosenthal, and our scientific and medical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business.

We conduct our operations at our facility in South San Francisco, California, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided and will continue to provide restricted stock, stock option grants, and other equity awards that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer.

### We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2021, we had 184 full-time employees. As our development plans and strategies develop, and as we continue to implement the requirements applicable to operating as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

identifying, recruiting, integrating, retaining, and motivating additional employees;
managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties;
expanding our operational, financial and management controls, reporting systems, and procedures; and
managing increasing operational and managerial complexity.

Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to manage these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals.

We have engaged in strategic collaborations and may in the future engage in acquisitions, collaborations, or strategic partnerships, which may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We have engaged in strategic collaborations in the past, such as our strategic collaborations with AbbVie and GSK, and we may engage in various acquisitions, collaborations, and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition, collaboration, or strategic partnership may entail numerous risks, including:

increased operating expenses and cash requirements;
volatility with respect to the financial reporting related to such arrangements, such as our expected variability in the recognition of revenue each quarter from the AbbVie Agreement and GSK Agreement based on the percentage-of-completion basis under the applicable accounting rules;
assumption of indebtedness or contingent liabilities;
issuance of our equity securities which would result in dilution to our stockholders;
assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;
diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer other breakdowns, cyberattacks, or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, result in material disruptions of our development programs and business operations, risk disclosure of confidential, financial, or proprietary information, and affect our reputation.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering, and/or other means. If a breakdown, cyberattack, or other information security breach were to occur and cause interruptions in our operations, it could result in a misappropriation of confidential information, including our intellectual property or financial information, and a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing, or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential, financial, or proprietary information, including data related to our personnel, we could incur liability or risk disclosure of confidential, financial, or proprietary information, and the further development and commercialization of our product candidates could be delayed. There can be no assurance

that we and our business counterparties will be successful in efforts to detect, prevent, or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business, or reputational harm to us.

# Business disruptions, including as a result of global pandemics, could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to pandemic events and the spread of disease, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, political unrest, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster, global pandemics, or other business interruption.

The majority of our operations including our corporate headquarters are located in a facility in South San Francisco, California. Damage or extended periods of interruption to our corporate, development, or research facilities due to fire, natural disaster, global pandemics, power loss, communications failure, unauthorized entry, or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

### Our business is subject to economic, political, regulatory, and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Some of our CDMOs are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
differing and changing regulatory requirements in non-U.S. countries;
challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
difficulties in compliance with non-U.S. laws and regulations;
changes in non-U.S. regulations and customs, tariffs, and trade barriers;
changes in non-U.S. currency exchange rates and currency controls;
changes in a specific country's or region's political or economic environment;
shipping of biologics/drugs;
trade protection measures, import or export licensing requirements, or other restrictive actions by U.S. or non-U.S. governments;
negative consequences from changes in tax laws;
compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
workforce uncertainty in countries where labor unrest is more common than in the United States;
difficulties associated with staffing and managing international operations, including differing labor relations;
potential liability under the FCPA, UK Bribery Act, or comparable foreign laws; and
business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

#### Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2020, we had federal and state net operating loss (NOL) carryforwards of approximately \$195.3 million and \$191.4 million, respectively, some of which have an indefinite life. Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. As a result of our initial public offering in February 2019 and follow-on public offering in January 2020, and other transactions that have occurred since our incorporation, we may have experienced such an ownership change. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset post-change taxable income or taxes may be subject to limitation. In addition, the enacted legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the Tax Act) imposes certain limitations on the deduction of NOLs. The Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act of 2020 (CARES Act), also provides that NOLs from tax years that began after December 31, 2017 may offset no more than 80% of current taxable income annually for taxable years beginning after December 31, 2020. Our NOLs may also be subject to limitations under state law. For example, California enacted legislation suspending the use of NOLs for taxable years 2020, 2021 and 2022 for many taxpayers.

#### **General Risk Factors**

### An active trading market for our common stock may not be sustained.

Prior to our initial public offering in February 2019, there was no public trading market for our common stock. Although our common stock is listed on the NASDAQ Global Select Market, the market for our shares has demonstrated varying levels of trading activity. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

### The market price of our common stock may continue to be volatile, which could result in substantial losses for investors.

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Some of the factors that may cause the market price of our common stock to fluctuate include:

the success of existing or new competitive products or technologies;
the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
commencement or termination of collaborations for our product development and research programs;
failure to achieve development, regulatory, or commercialization milestones under our collaborations;
failure or discontinuation of any of our product development and research programs;
results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
regulatory or legal developments in the United States and other countries;
developments or disputes concerning patent applications, issued patents, or other proprietary rights;
the recruitment or departure of key personnel;
the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop;
the results of our efforts to develop additional product candidates or products;
actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
announcement or expectation of additional financing efforts;
64

П	sales of our common stock by us, our insiders, or other stockholders, such as if we use our at-me-market facility,
	expiration of market standoff or lock-up agreements;
	variations in our financial results or those of companies that are perceived to be similar to us;
	changes in estimates or recommendations by securities analysts, if any, that cover our stock;
	changes in the structure of healthcare payment systems;
	market conditions in the pharmaceutical and biotechnology sectors;
	general economic, industry, and market conditions; and
П	the other factors described in this "Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

## If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business cease to cover us or downgrade their evaluations of our stock or if we fail to meet their operating results estimates for us, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

# Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amount of our common stock in the public market, the market price of our common stock could decline significantly.

Certain holders of shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price for our common stock.

# Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing such securities. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. On May 13, 2020, we filed a shelf registration statement on Form S-3 with the SEC that automatically became effective and permits us to use our at-the-market facility for sales of up to \$150 million worth of shares of common stock from time to time.

Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

## Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, may significantly influence all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe is in their best interests. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

# We have incurred and will continue to incur significant additional costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform, and Consumer Protection Act, the listing requirements of NASDAQ, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have hired, and expect that we will need to continue to hire, additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel have devoted and will continue to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to maintain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

## If we are unable to maintain effective internal controls, our business, financial position, and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Exchange Act, including the requirements of Sarbanes-Oxley Act Section 404(a), which require annual management assessments of the effectiveness of our internal control over financial reporting. Section 404(b) of the Sarbanes-Oxley Act also requires our independent auditors to attest to, and report on, this management assessment.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm are unable to attest to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, which would require additional financial and management resources.

### We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our charter documents:

establish that our board of directors is divided into three classes, Class I, Class II, and Class III, with each class serving staggered three-year terms;
provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
provide that our directors may only be removed for cause;
eliminate cumulative voting in the election of directors;
authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
provide our board of directors with the exclusive right to elect a director to fill a vacancy or newly created directorship;
permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
prohibit stockholders from calling a special meeting of stockholders;
require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
authorize our board of directors, by a majority vote, to amend the bylaws; and
require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated 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 employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware)

is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the
jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such
determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter
jurisdiction):

	any derivative action or proceeding brought on our behalf;
	any action asserting a claim of breach of fiduciary duty;
	any action asserting a claim against us arising under the DGCL, our amended- and restated certificate of incorporation or our amended and restated bylaws; and
П	any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These exclusive-forum provisions 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 lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

#### **Use of Proceeds**

The Registration Statement on Form S-1 (File No. 333-229152) was declared effective by the SEC for our initial public offering of common stock on February 6, 2019. We started trading on the NASDAQ Global Select Market on February 7, 2019. In connection with our initial public offering, we sold an aggregate of 9,739,541 shares of common stock at a public offering price of \$19.00 per share, including 489,541 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares. The underwriters for our initial public offering were Morgan Stanley & Co. LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Cowen and Company, LLC. The aggregate net proceeds received by the Company from the offering, net of underwriting discounts and commissions and offering expenses, were \$168.2 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

We filed the Registration Statement on Form S-1 (File No. 333-236094) for issuing additional shares as part of a secondary public offering. The Registration Statement was declared effective by the SEC on January 29, 2020. We sold an aggregate of 9,602,500 shares of common stock at a public offering price of \$25.00 per share, including 1,252,500 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares. The underwriters for our secondary public offering were Morgan Stanley & Co. LLC, Goldman Sachs & Co. LLC, BofA Securities, Inc., and Cowen and Company, LLC. The aggregate net proceeds received by the Company from the offering, net of underwriting discounts and commissions and offering expenses, were \$224.5 million. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in the planned use of proceeds from our public offerings as described in our final prospectuses filed with the SEC on February 7, 2019 and January 30, 2020, respectively, pursuant to Rule 424(b)(4). We invested the funds received in interest-bearing, investment-grade securities and government securities, corporate bonds, and commercial paper.

#### Item 6. Exhibits.

#### **Exhibit Index**

			Incorporated	by Reference		
					Filing	Filed
Number	Exhibit Title	Form	File No.	Exhibit	Date	Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-38792	3.1	2/11/2019	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-38792	3.1	10/6/2020	
10.19+	Collaboration and License Agreement, dated July 1, 2021, by and between Glaxo Wellcome UK Limited and Alector, Inc.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes- Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document: the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.					X

<sup>\*</sup> The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

<sup>+</sup> Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

## **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.

## ALECTOR, INC.

Date: August 3, 2021 By: /s/ Arnon Rosenthal

Arnon Rosenthal, Ph.D.

Co-founder and Chief Executive Officer

(Principal Executive Officer)

Date: August 3, 2021 By: /s/ Calvin Yu

Calvin Yu

Vice President, Finance

(Principal Financial and Accounting Officer)

\*\*\* Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

## COLLABORATION AND LICENSE AGREEMENT

**BY AND BETWEEN** 

ALECTOR, INC.

**AND** 

GLAXO WELLCOME UK LIMITED

## **Table of Contents**

1

ARTICLE I DEFINITIONS

ARTICLE	II MANAGEMENT OF COLLABORATIVE ACTIVITIES	30
2.1 2.2 2.3 2.4 2.5 2.6 2.7 2.8 2.9	Joint Steering Committee. Joint Development Committee. Joint Manufacturing Committee. Joint Patent Committee. Joint Commercialization Committee. Working Groups. Membership. Decision-Making. Meetings of the JSC, JDC, JMC, JPC, JCC and Working Groups.	30 31 32 32 33 34 37 37
2.10 2.11	Discontinuation of Joint Committees. Alliance Managers.	39 39
ARTICLE	III LICENSE GRANTS	40
3.1 3.2 3.3 3.4 3.5 3.6 3.7 3.8 3.9 3.10	Alector Grants. GSK Grants. Sharing of Data and Know-How and Materials. Sublicensing. Alector Covenants. GSK Covenants. Acquisition of Competing Product. Section 365(n) of the Bankruptcy Code. Retention of Rights. Joint Patents.	40 40 41 43 44 45 45 46 46 46
ARTICLE	IV DEVELOPMENT	47
4.1 4.2 4.3 4.4 4.5 4.6 4.7	General. GDP; Non-Core GDP; Amendments; Development Responsibilities. Development Efforts; Manner of Performance; Reports. Regulatory Submissions and Regulatory Approvals. Costs of Joint Development. New Product Decisions. Patient Samples. Progranulin Gene Therapy Program.	47 48 53 57 59 65 67 68
ARTICLE	V COMMERCIALIZATION	70
5.1 5.2 5.3 5.4	Commercialization Efforts.  Manner of Performance.  Commercialization Plans.  Medical Affairs Responsibilities.	70 75 77 80
	2	

5.5	Advertising and Promotional Materials for Cost Profit Sharing Products.		81
<b>5.6</b>	Product Packaging.		82
<b>5.7</b>	Sales and Distribution.		82
<b>5.8</b>	Co-Promotion of Cost Profit Sharing Products in the United States.		83
<b>5.9</b>	Training.		84
5.10	Management of Sales Representatives.		85
5.11	Other Responsibilities.		85
5.12	Adverse Event and Product Complaint Reporting Procedures; Notice of Information Marketability of the Licensed Product.	Affecting	86
5.13	Recalls, Market Withdrawals or Corrective Actions.		86
5.14	Medical Inquiries.		87
5.15	Early Access Programs.		87
5.16	Field Based Representatives.		87
5.17	Compliance.		89
ARTICLE VI	MANUFACTURE AND SUPPLY		89
6.1	Manufacture.		89
6.2	Manufacturing Transfer.		93
6.3	CMC Development.		93
6.4	Supply and Quality Agreement.		94
	FINANCIAL PROVISIONS		94
7.1	Upfront Payment.		94
7.2	Milestone Payments.		94
7.3	U.S. Pre-Tax Profit or Loss.		99
7 <b>.</b> 4	OUS Territory Royalties and Opt Out Product Royalties.		99
7. <del>-</del> 7.5	Royalty Reporting and Payment.		103
7.6	Quarterly Reconciliation and Payments.		103
7.7	Blocking Third Party Technology.		105
7.8	Existing Third Party Agreement Payments.		105
7 <b>.</b> 9	Audits.		106
7.10	Withholding Taxes.		107
7.11	Indirect Taxes.		108
7.12	Tax Matters.		109
7.13	Tax Information.		109
7.14	Currency Exchange.		109
7.15	Late Payments.		110
7.16	Resolution of Financial Disputes.		110
	I INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS		110
8.1	Ownership of Inventions.		110
8.2	Prosecution and Maintenance of Patents Globally.		111
8.3	Third Party Infringement.		113
8.4	Patent Invalidity Claim.		116

3

<sup>\*\*\*</sup> Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

8.5 8.6 8.7	Claimed Infringement. Patent Term Extensions. Trademarks.	117 118 118
ARTICLE I	X CONFIDENTIALITY AND PUBLICITY	119
9.1 9.2 9.3 9.4 9.5	Confidential Information. Recipient Obligations. Confidential Terms. Publicity. Publications.	119 121 121 121 122
	K REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS	123
10.1 10.2 10.3 10.4 10.5 10.6 10.7 10.8 10.9 10.10 10.11 10.12 10.13	Representations of Authority. Consents. No Conflict. Enforceability. Additional Mutual Representations and Warranties. Additional Representations and Warranties of Alector. Existing Third Party Agreements. No Warranties. No Debarment. Compliance with Anti-Corruption Laws. Insurance. Data Privacy and Security. Post-Closing Covenants.	123 123 124 124 124 127 127 128 128 129 130
	XI INDEMNIFICATION	130
11.1 11.2 11.3 11.4 11.5	General Indemnification By Alector. General Indemnification By GSK. Product Liability Costs. Claims for General Indemnification. Conduct of Product Liability Claims.	130 131 131 132 132
ARTICLE 2	KII TERM AND TERMINATION	133
12.1 12.2 12.3 12.4 12.5 12.6	Term. Termination For Material Breach. Termination for Patent Challenge. Termination for Insolvency. Termination by GSK Unilaterally. Effects of Termination.	133 133 135 135 136 136
ARTICLE 2	XIII DECISION-MAKING; DISPUTE RESOLUTION	143
13.1 13.2 13.3	Referral to Executive Officers.  Decisions to Terminate or Suspend a Study Based on Safety Concerns.  Resolution of Certain Disputes.	143 143 144

144

<sup>\*\*\*</sup> Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

13.4	Arbitration.	149
ARTICLE XI	V MISCELLANEOUS	150
14.1	Assignment; Successors.	150
14.2	Alector Change of Control.	151
14.3	Choice of Law.	153
14.4	Notices.	153
14.5	Severability.	154
14.6	Integration.	155
14.7	Waiver and Non-Exclusion of Remedies.	155
14.8	Independent Contractors; No Agency.	155
14.9	Submission to Jurisdiction.	155
14.10	Execution in Counterparts; Facsimile Signatures.	156
14.11	No Consequential or Punitive Damages.	156
14.12	Performance by Affiliates.	156
14.13	Force Majeure.	156
14.14	Further Assurance.	157
14.15	Construction.	157
14.16	HSR Filings and Closing.	157

## **Exhibits**

Exhibit 1.8 Initial Alector Patents

Exhibit 1.47 Existing Third Party Agreements

Exhibit 1.51 Financial Exhibit

Exhibit 1.58 Initial Global Development Plan

Exhibit 4.5.4(b) [\*\*\*]

Exhibit 5.17.1 Compliance Program

Exhibit 6.1.2(e) Existing Manufacturing Contracts

Exhibit 6.2 Manufacturing Transfer Principles

Exhibit 9.4.1 Press Releases

Exhibit 10.6 Certain Exceptions to Representations

5

<sup>\*\*\*</sup> Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

#### COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is made and entered into as of the 1st day of July, 2021 (the "**Execution Date**") by and between Alector, Inc., a Delaware corporation, with offices at 131 Oyster Point Blvd., Suite 600, South San Francisco, CA 94080 ("**Alector**") and Glaxo Wellcome UK Limited, a private company limited by shares organized under the laws of England having an office at 980 Great West Road, Brentford, Middlesex TW8 9GS, England, registered under company number 00480080 ("**GSK**").

#### **INTRODUCTION**

WHEREAS, Alector is developing certain Licensed Antibodies and Licensed Products (as defined below), and Controls (as defined below) certain intellectual property and other rights with respect to such Licensed Antibodies;

WHEREAS, Alector and GSK believe that a collaboration and license arrangement between the Parties regarding the Licensed Antibodies and Licensed Products would be desirable;

WHEREAS, the Parties desire to collaborate on the Development of the Licensed Antibodies and Licensed Products, with GSK taking the lead on Phase III Clinical Studies for Major Indications and Alector taking the lead with respect to other Development activities, in each case in accordance with the terms and conditions set forth in this Agreement;

WHEREAS, the Parties desire to co-commercialize the Licensed Product in the United States and desire GSK to lead the Commercialization of the Licensed Products in the OUS Territory, in each case in accordance with the terms and conditions set forth in this Agreement; and

NOW, THEREFORE, in consideration of the mutual promises and conditions contained herein, and other good and valuable consideration, Alector and GSK hereby agree as follows:

# ARTICLE I DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth below:

- **1.1** "Accounting Standards" means, with respect to a Party or Selling Entity and its Affiliates (a) the United States Generally Accepted Accounting Principles or (b) International Financial Reporting Standards as adopted by the European Union or, following the withdrawal of the United Kingdom from the European Union, as adopted by the United Kingdom, in each case ((a) and (b)), as such Party or Selling Entity uses for its financial reporting obligations, consistently applied.
- **1.2** "Action" means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil, criminal or administrative),

6

controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

- **1.3** "Affiliate" means with respect to any Party, any Person controlling, controlled by or under common control with such Party. For purposes of this Section 1.3, "control" means (i) in the case of a Person that is a corporate entity, direct or indirect ownership of more than 50% of the stock or shares having the right to vote for the election of directors of such Person or (ii) in the case of a Person that is an entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.
  - 1.4 "AL001" means Alector's anti-sortilin clinical-stage Antibody designated as AL001 by Alector.
  - 1.5 "AL101" means Alector's anti-sortilin clinical-stage Antibody designated as AL101 by Alector.
- <u>1.6</u> "Alector Intellectual Property" means Alector Know-How, Alector Patents, Alector's interest in the Joint Patents, Alector Sole Inventions, and Alector Platform Patents, collectively.
  - **1.7 "Alector Know-How"** means any Know-How [\*\*\*].
- **1.8** "**Alector Patents**" means Patents (excluding Joint Patents) that [\*\*\*]. A list of Alector Patents existing as of the Execution Date and [\*\*\*] is attached hereto as Exhibit 1.8 (the "**Initial Alector Patents**").
  - **1.9** "Alector Product Patent" means [\*\*\*].
- **1.10** "Approved Labeling" means, with respect to a Cost Profit Sharing Product: (a) the Regulatory Authority-approved full prescribing information for such Cost Profit Sharing Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Cost Profit Sharing Product.
- <u>1.11</u> "Antibody(ies)" means an immunoglobulin (Ig) molecule, or other composition comprising an amino acid based structure, in each case that binds or incorporates one or more moieties capable of binding a target, including any such composition containing a scaffold based on an Ig molecule or a fragment, alternative form or derivative thereof, or any other amino acid containing structures [\*\*\*], in each case that bind or incorporate one or more moieties capable of binding a target. Notwithstanding the foregoing, Antibodies shall exclude synthetic chemical compositions with [\*\*\*].
- **1.12** "**Biosimilar Product**" means, on a country-by-country basis, a biologic product that has a substantially similar active substance as a Licensed Antibody and (a) whose licensing, approval,

7

or marketing authorization relies [\*\*\*] (b) is determined (i) by the FDA to be biosimilar or interchangeable with a Licensed Product as set forth at 42 USC 262(k), (ii) by a Regulatory Authority in the EU to be a generic medicinal product of a Licensed Product as set forth in EU Directive 2001/83/EC (as amended, including by EU Directive 2004/27/EC), or (iii) by a Regulatory Authority outside of the United States and the EU in a manner equivalent to the foregoing clause (i) or (ii), whether referred to as a biosimilar, follow-on biologic or generic biological product or otherwise, in such jurisdiction. [\*\*\*].

## 1.13 "Blocking Third Party Technology" means [\*\*\*].

- <u>1.14</u> "Business Day" means a day on which banking institutions in San Francisco, California and London, United Kingdom are open for business, but in any event excluding the nine (9) consecutive calendar days beginning on December 24<sup>th</sup> and continuing through January 1<sup>st</sup> of each calendar year during the Term.
- <u>1.15</u> "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.
- <u>1.16</u> "Calendar Year" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.
- <u>1.17</u> "Clinical Investigation Laws" means Laws relating to human clinical investigations, including 21 C.F.R. Parts 50, 54, 56 and 312, and then-current Good Clinical Practice, each as in effect and as amended from time to time.
- <u>1.18</u> "Clinical Studies" means collectively any Phase I Clinical Studies, Phase II Clinical Studies, Phase III Clinical Studies and Phase IV/Post-Approval Clinical Studies, and any other study in which human subjects are dosed with a drug, whether approved or investigational, in each case of a Licensed Product within the Field.
- **1.19** "CMC Development" means the following Development activities: test method development and stability testing, process development, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, and other related activities, in each case pertaining to Development of a process to Manufacture Licensed Antibodies or Licensed Products.

8

- 1.20 "Collaboration Activities" means activities in the Development, Manufacture or Commercialization of (a) an Existing Antibody or Existing Product or (b) any other Licensed Antibody or Licensed Product for which there has been an approved New Product Decision in accordance with Section 4.6, in each case (a) and (b) performed in the course of conducting the GDP under this Agreement.
- **1.21** "Collaboration Intellectual Property" means any and all (i) Data and Know-How that is made, generated or obtained by or on behalf of either Party (or both Parties) or their Affiliates, or the Subcontractors and other Third Party contractors of any of them (to the extent the applicable Data and Know-How is Controlled by the applicable Party or its Affiliate) in the course of performing Collaboration Activities, including, for the avoidance of doubt, inventions described in clause (ii), and (ii) Patents in and to inventions made in whole or part by either Party (or both Parties) or their Affiliates, or the Subcontractors and other Third Party contractors of any of them (to the extent the applicable invention or Patents are Controlled by the applicable Party or its Affiliate) in the course of performing Collaboration Activities (such Patents, "Collaboration Patents").
- **1.22** "Combination Product" means a Licensed Product that is comprised of or contains one (1) or more Licensed Antibodies as an active ingredient together with one (1) or more Other Active Ingredients, either co-formulated or packaged together and sold as a single unit for a single price.
- <u>1.23</u> "Commercialization" or "Commercialize" means activities directed to obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing, selling or offering for sale a product and interacting with Regulatory Authorities regarding any of the foregoing other than for obtaining Regulatory Approval. Commercialization shall not include any activities related to Development or Manufacturing.
  - **1.24** "Commercially Reasonable Efforts" means [\*\*\*].
  - 1.25 "Competing Product" means [\*\*\*].
- <u>1.26</u> "Control" or "Controlled" means, with respect to a Party, the possession (whether by license or ownership, or by control over an Affiliate having possession by license or ownership) by such Party of (a) with respect to any intellectual property right or other intangible property, the ability to grant to the other Party access or a license or sublicense as provided herein without violating the terms of any agreement with any Third Party and (b) with respect to any tangible material or other item, the legal authority or right to physical possession of such tangible material or item, with the right to provide such tangible material or item to the other Party on the terms set forth herein.
- **1.27** "**Core Dossier**" means the Data intended for use in obtaining Regulatory Approval of a Licensed Product in the [\*\*\*]. For clarity, Data included in the Core Dossier may be used in support of obtaining Regulatory Approval of a Licensed Product [\*\*\*].

- **1.28** "Cost Profit Sharing Product" means any (i) Existing Antibody or Existing Product or (ii) any other Licensed Antibody or Licensed Product for which there has been an approved New Product Decision in accordance with Section 4.6, in each case other than an Opt Out Product.
- **1.29** "Cover," "Covering" or "Covered" means, with respect to a Licensed Product or with respect to technology, that, in the absence of a license granted under or ownership of a Valid Claim, the making, use, offering for sale, sale, or importation of such Licensed Product or the practice of such technology would or is reasonably likely to infringe such Valid Claim (as if issued with respect to any Valid Claim that is not issued).
- 1.30 "Data" means any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws) and the like, in each case directed to, or used in the Development, Manufacture or Commercialization of any Licensed Antibody or Licensed Product hereunder.
- **1.31 "Data Security and Privacy Laws**" shall mean all applicable Laws related to data protection and privacy, including, to the extent applicable, the EU Data Protection Laws, the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and any supranational, federal, state, or national legislation relating to Personally Identifiable Information or privacy that is applicable to a Party relating to the processing of Personally Identifiable Information.
- 1.32 "Development" or "Develop" means non-clinical and clinical research and drug development activities, including toxicology, pharmacology and other discovery efforts, test method development and stability testing, assay development, cell line development, process development and improvement, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Studies (including preapproval studies and Post-Approval Required Studies, but excluding Post-Approval Optional Studies and Investigator Sponsored Clinical Studies), regulatory affairs, and Regulatory Approval and Clinical Study regulatory activities (excluding regulatory activities directed to obtaining pricing and reimbursement approvals) and all other activities, including any post-marketing commitments, necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval and, to the extent not included in the foregoing, any other activities set out in the Global Development Plan.
- **1.33** "Development Budget" means the budget for conducting Development of Cost Profit Sharing Products (including Manufacturing activities performed in connection therewith) in support of the Core Dossier pursuant to the GDP (a) during a given Calendar Year (in reasonable detail and broken down by Calendar Quarter), (b) a good faith forecasted budget, in reasonable detail, for the [\*\*\*] (broken down by Calendar Year), and (c) a good faith forecasted budget for

such Development through approval in [\*\*\*] for each Indication then included in the GDP, or, if later, until the end of the time period covered by the approved GDP all as developed by the JDC and approved by the JSC in accordance with Section 4.2.3, which budget shall be updated and amended concurrently with the GDP in accordance with Section 4.2.5.

- **1.34** "Development Costs" means FTE Costs and Out-of-Pocket Costs incurred [\*\*\*]
- **1.35** "Development FTE" means an FTE performing Development activities under the GDP.
- **1.36** "**Divest**" means, with respect to a product, (a) the sale, exclusive license or other transfer by the applicable Party and its Affiliates of all of their Development and Commercialization rights with respect to such product to a Third Party without the retention or reservation of any Commercialization interest or participation rights (other than [\*\*\*]) or [\*\*\*].
- <u>1.37</u> "**Drug Regulation Laws**" means Laws regulating the distribution of biologics, drugs and pharmaceutical products, including the FFDCA, the Prescription Drug Marketing Act of 1987, the federal Controlled Substances Act, 21 U.S.C. § 801 *et. seq.*, and policies issued by the FDA, as well as similar Laws in the OUS Territory, each as in effect and as amended from time to time.
- **1.38** "Early Access Program" or "EAP" means any program to provide patients with a Licensed Product prior to Regulatory Approval and prior to First Commercial Sale [\*\*\*]. Early Access Programs include Treatment INDs / Protocols, named patient programs and compassionate use programs and similar programs in other countries. For clarity, an EAP with respect to a Licensed Product may continue to be performed following Regulatory Approval of such Licensed Product and costs may continue to be incurred in accordance with the performance of such EAP after Regulatory Approval.
  - **1.39** "Effective Date" means the first Business Day following the HSR Clearance Date.
- **1.40** "EMA" means the European Medicines Agency or any successor agency thereto and, with respect to any Regulatory Approval in the European Union, includes the European Commission.
- **1.41** "EMA Territory" means, with respect to an MAA filed under the centralized EMA filing procedure, the European Union.
- **1.42** "European Union" or "EU" means the countries of the European Union, as it is constituted on the Effective Date and as it may be altered from time to time after the Effective Date.

11

- **1.43** "EU Data Protection Law" (a) the GDPR; (b) the Privacy and Electronic Communications Directive 2002/58/EC; (c) the UK Data Protection Act 2018 ("UK DPA"), the UK General Data Protection Regulation as defined by the UK DPA as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019, and the Privacy and Electronic Communications Regulations 2003; (d) any equivalent legislation in any jurisdiction in which either Party is established; and (e) any relevant law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding instrument which implements any of the above or which otherwise relates to data protection, privacy or the use of personal data, in each case as applicable and in force from time to time, and as amended, consolidated, reenacted or replaced from time to time.
- **1.44** "Executive Officers" means [\*\*\*]. In the event that the position of any of the Executive Officers identified in this Section 1.44 no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer shall be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.
  - **1.45** "Existing Antibody" means AL001 or AL101.
- **1.46** "Existing Product" means any product containing an Existing Antibody as formulated by Alector for use in its Clinical Studies of an Existing Antibody prior to the Effective Date.
  - **1.47** "Existing Third Party Agreements" means the agreements listed on Exhibit 1.47.
  - **1.48 "FDA"** means the United States Food and Drug Administration or any successor agency thereto.
- **1.49** "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).
  - **1.50 "Field"** means any use or purpose, including the treatment, palliation, diagnosis or prevention of any human disease.
  - **1.51 "Financial Exhibit"** means **Exhibit 1.51** attached hereto, as the same may be amended from time to time by the Parties.
- <u>1.52</u> "First Commercial Sale" means, with respect to a Licensed Product in a country, the first commercial sale of such Licensed Product in the Field in such country for sale to, or use or consumption by, an end user following Regulatory Approval of such Licensed Product. Sales for Clinical Study purposes, Early Access Programs or similar uses shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between a Party and its Affiliates

and Sublicensees, or between the Parties (or their respective Affiliates or Sublicensees), shall not constitute a First Commercial Sale.

- **1.53** "Force Majeure Event" shall mean any acts or events beyond a Party's reasonable control, including strikes or other labor disturbances, lockouts, insurrections, riots, quarantines, epidemics, pandemics and other communicable disease outbreaks (including COVID-19 and any variants thereof), government actions, acts of God, embargoes, wars, acts of war (whether war be declared or not), acts of terrorism, fires, earthquakes, floods or storms, or impossibility to obtain materials, components, drug substance, drug product, utilities, equipment, supplies, fuel or other required materials.
- 1.54 "FTE" means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [\*\*\*] ([\*\*\*]) hours per Calendar Year) of work directly performing activities for a Licensed Antibody or Licensed Product. Any person who devotes less than [\*\*\*] ([\*\*\*]) hours per Calendar Year (or such other number as may be agreed by the JDC or JCC, as applicable) shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [\*\*\*] ([\*\*\*]). Overtime, and work on weekends, holidays, and the like will not be counted with any multiplier (e.g., time-anda-half or double time) toward the number of hours that are used to calculate the FTE contribution. The Parties shall utilize fractions of FTEs, as applicable.
- **1.55 "FTE Costs"** means, as applicable with respect to any period, the FTE Rate multiplied by the number of FTEs performing Development activities and Commercialization activities under this Agreement, respectively, during such period. FTEs billable by a Party for one individual during a given Calendar Quarter will be expressed as the fraction of that individual's time which has been coded to the activities for that period as captured in the Party's effort tracking system for such period. For example, assuming a [\*\*\*] hour work year, and a FTE:
  - If effort is tracked on an hourly basis, a quarterly report would multiply the number of hours worked in the quarter by an hourly FTE rate of [\*\*\*] ([\*\*\*]). For an employee working [\*\*\*] on a collaboration activity in a quarter, the calculation would be [\*\*\*].
  - If effort is tracked on a monthly basis, a quarterly report would multiply the number of person months worked in the quarter by a quarterly FTE rate of [\*\*\*] ([\*\*\*]). For an employee working [\*\*\*] research person months on a GDP activity in a quarter, the calculation would be [\*\*\*].
- **1.56 "FTE Rate"** means, unless otherwise agreed by the unanimous decision of the Finance Working Group or mutually by the Parties in writing, commencing on the Effective Date the following rates:

13

Category	FTE Rate
[***]	[***]

[\*\*\*]

- **1.57** "GDPR" shall mean Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.
- <u>1.58</u> "Global Development Plan" or "GDP" means the plan for the Parties' worldwide Development activities with respect to the conduct of GLP toxicology studies or other studies to support IND filing of a Cost Profit Sharing Product and any Clinical Studies of a Cost Profit Sharing Product in the Field in support of the Core Dossier, including the Development Budget, as amended from time to time in accordance with the terms of this Agreement. The initial GDP is attached hereto as <u>Exhibit 1.58</u> ("Initial GDP").
- **1.59** "Good Clinical Practice" means (a) the then-current good clinical standards, practices and procedures promulgated or endorsed by the FDA or other Governmental Authority, as set forth in the guidelines adopted by the ICH, titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," (or any successor document), (b) the Declaration of Helsinki (2013) as last amended at the  $64^{th}$  World Medical Association in October 2013 and any further amendments or clarifications thereto and (c) related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, to the extent such standards are not less stringent than United States good clinical standards, in each case (a) (c) as may be amended and applicable from time to time.
- <u>1.60</u> "Good Laboratory Practice" means the then-current good laboratory standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA, or other Regulatory Authority applicable to the Territory, to the extent such standards are not less stringent than United States good laboratory standards, in each case, as may be amended and applicable from time to time.
- **1.61** "Good Manufacturing Practice" means all applicable Good Manufacturing Practices, including: (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice; (b) the principles detailed in the U.S. Current Good

14

Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601, 610 and 820; (c) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products; (d) the principles detailed in the ICH Q7A guidelines; and (e) the equivalent Laws in any relevant country, in each case, as may be amended and applicable from time to time.

- **1.62** "Governmental Authority" means any United States federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- <u>1.63</u> "Government Health Care Programs" means the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), TRICARE (10 U.S.C. § 1071 et seq.), and the Federal Employee Health Benefits Program, in each case in the United States, and other foreign, federal, state and local governmental health care plans and programs in the OUS Territory.
- <u>1.64</u> "Government Order" means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority.
- **1.65** "GSK Intellectual Property" means GSK Know-How, GSK Patents, GSK's interest in the Joint Patents, and GSK Sole Inventions, collectively.

1.66 "GSK Know-How" means any Know-How [\*\*\*].

**1.67 "GSK Manufacturing Know-How"** means any [\*\*\*].

**1.68** "GSK Patents" means Patents (excluding Joint Patents) that [\*\*\*].

1.69 "Health Care Laws" means Laws relating: (a) to Government Health Care Programs, including the federal Medicare statute (Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh, including the amendments implemented by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Medicare Improvements for Patients and Providers Act of 2008), the federal Medicaid statute (Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v), the Veterans Health Care Act of 1992 and the federal TRICARE statute (10 U.S.C. § 1071 et seq.) and federal Laws pertaining to the Federal Employee Health Benefit Program, (b) Private Health Care Plans, (c) privacy and confidentiality of patient health information and human biological materials, including, in the United States, HIPAA (the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and any regulations promulgated thereunder), (d) fraud and abuse, self-referral, anti-kickback, and false claims laws, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the federal Physician Self-Referral (Stark) Law (42 U.S.C. § 1395nn), the civil False Claims Act (31 U.S.C. § 3729 et seq.), the criminal False Claims

15

Act (42 U.S.C. § 1320a-7b(a)), as amended, the federal Exclusion statute (42 U.S.C. § 1320a-7), the federal Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), Beneficiary Inducement Statute (42 U.S.C. § 1320a-7 a(a)(5)), the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) and the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h); (e) price reporting, government contracting, and the processing of any applicable rebate, chargeback or adjustment, including the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8), VA Federal Supply Schedule (38 U.S.C. § 8126), Medicare average sales price reporting (, 42 U.S.C. § 1395w-3a), the Public Health Service Act, (42 U.S.C. § 201 *et. seq.*); or under any state, provincial or territorial pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government program, in the case of each of the foregoing clauses, as amended and together with the regulations pursuant to such Laws, and (f) as similar Laws in the OUS Territory, each as in effect and as amended from time to time.

- **1.70 "ICH"** means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
  - **1.71** "**Indication**" means [\*\*\*].
  - 1.72 "Indication Category" means either all Major and Related Indications or all Non-AD/PD Minor Indications.
- **1.73** "IND" means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application or a clinical trial exemption, or any other equivalent or related regulatory submission, license or authorization.
  - **1.74** "**Initiation**" means, with respect to a Clinical Study, the [\*\*\*] for such trial.
- <u>1.75</u> "Investigator Sponsored Clinical Study" means a human clinical study of a Licensed Product that is sponsored and conducted by a Third Party, pursuant to an IND owned by such Third Party, under an agreement with a Party or its Affiliate pursuant to which such Party or such Affiliate provides clinical supplies of the Licensed Product or funding for such clinical study.
  - **1.76** "Joint Patents" means Patents that Cover Joint Inventions.
- **1.77** "**Know-How**" means (a) any information, whether proprietary or not and whether patentable or not, including [\*\*\*] (b) any information in Materials.
  - **1.78** "**Knowledge**" means, with respect to a Party, [\*\*\*].
- **1.79** "Last Agreed Budget" means, at a given time, the most recent Development Budget at such time agreed by both Parties, themselves, through the representatives of both Parties on the JSC or the Executive Officers pursuant to Section 13.1, or established by the Finance Working

16

Group pursuant to Section 4.5.4(e) (and for clarity, not determined pursuant to Sections 13.3.1(a)(c) or 13.4).

- **1.80** "Launch Window" means, for any Cost Profit Sharing Product, the period commencing (a) [\*\*\*] and ending (b) [\*\*\*].
- <u>1.81</u> "Law" means any United States federal, state or local or foreign or multinational law, statute, Guideline, OIG advisory opinion, standard, ordinance, code, rule, regulation, resolution or promulgation, or any Government Order, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.
  - **1.82** "Licensed Antibody" means (a) AL001, (b) AL101, (c) [\*\*\*] and (d) [\*\*\*]. For purposes of the foregoing, [\*\*\*].
- **1.83** "Licensed Product" means any product that contains any Licensed Antibody, in any dosage form, formulation, or method of delivery.
- **1.84** "MAA" means a Biologics License Application as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.
  - **1.85** "Major European Country" means any of the France, Germany, Italy, Spain, or the United Kingdom.
  - **1.86 "Major Indication"** means any Indication with a patient prevalence of more than [\*\*\*] in the United States.
- **1.87** "Manufacturing" or "Manufacture" means all activities directed to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, serialization, labeling, shipping, and holding of any product, or any component or intermediate thereof, including process development, process qualification and validation, scale-up, qualification, validation, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control. "Manufacturing" shall have a correlative meaning.
  - **1.88** "Manufacturing Costs" means Out-of-Pocket Costs and FTE Costs incurred [\*\*\*].
- <u>1.89</u> "Materials" means chemical or biological substances, including any biological or chemical compounds, drug products, Patient Samples, articles of Manufacture, or other materials, regardless of the route of transfer, that are supplied (or are to be supplied) by a Party or its nominee to the other Party or its nominee for use in the conduct of activities under this Agreement, including activities set forth in the Global Development Plan.

17

- **1.90** "Material Subcontract" means any Subcontract which the subcontracting Party (or Affiliate) anticipates at time of execution will entail total payments to the Subcontractor in excess of [\*\*\*] with respect to subcontracted activities under this Agreement, but excluding [\*\*\*].
- **1.91** "**Medical Affairs**" means, with respect to a product, any and all activities performed by or on behalf of a Party's or its Affiliates' medical affairs departments interacting with physicians or other healthcare professionals who may utilize or conduct research related to a drug or biological product, including: [\*\*\*].
- **1.92** "Medical Affairs Content" means all written, printed, graphic, electronic, audio or video matter, in each case, intended for use or used by a Party or its Affiliates, Sublicensees or subcontractors in connection with the conduct of Medical Affairs activities related to the Licensed Products in the United States.
- **1.93** "**Medical Affairs Materials**" means the Medical Affairs Content, Regulatory Filings relating to Medical Affairs Content, training program and related materials contemplated by paragraph 5.4.4, and prepared scientific and medical information responses for use in responding to medical questions or inquiries from members of the medical profession contemplated by Section 5.14.
  - ${f 1.94}$  "Minor Indication" means any Indication other than a Major Indication. [\*\*\*]

1.95 [\*\*\*]

**1.96** "Net Sales" means [\*\*\*].

**1.97** "**Non-Core GDP**" means the plan for GSK's worldwide Development activities with respect to the conduct of GLP toxicology studies or other studies to support IND filing and any Clinical Studies, in each case for (a) a Cost Profit Sharing Product in the Field that are not in support of the Core Dossier (*i.e.*, that are specific to a country outside of [\*\*\*]) or (b) an Opt Out Product, as amended from time to time in accordance with the terms of this Agreement.

1.98 "Other Active Ingredient" means [\*\*\*].

**1.99** "OUS Territory" means worldwide, excluding the United States.

1.100 "Out-of-Pocket Costs" means [\*\*\*].

1.101 "Parties" means Alector and GSK.

1.102 "Party" means either Alector or GSK.

<u>1.103</u> "Patents" means (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from

18

such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)), and (e) any similar rights, [\*\*\*].

- **1.104** "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
  - **1.105 "Personal Data"** shall have the same meaning as in the EU Data Protection Laws.
- **1.106** "Personally Identifiable Information" means any information that identifies or can be used to identify a natural person, including any information defined as "personally identifiable information," "personal information," "protected health information," or "nonpublic personal information" under applicable Laws, including, solely with respect to individuals afforded protections under the EU Data Protection Laws, Personal Data.
- <u>1.107</u> "Phase I Clinical Study" means any study in humans the principal purpose of which is preliminary determination of safety in healthy individuals or patients as described under 21 C.F.R. §312.21(a) with respect to the United States, or, with respect to a jurisdiction other than the United States, a similar clinical study.
- <u>1.108</u> "Phase II Clinical Study" means a preliminary efficacy and safety or dose ranging human clinical study of a Licensed Product in the target patient population, as described under 21 C.F.R. §312.21(b) with respect to the United States, or, with respect to a jurisdiction other than the United States, a similar clinical study.
- <u>1.109</u> "Phase III Clinical Study" means a human clinical study designed as a pivotal study to confirm with statistical significance the efficacy and safety of a Licensed Product with respect to a given Indication, which study is performed for purposes of filing an MAA or similar application to obtain Regulatory Approval for such Licensed Product for such Indication in any country, including a clinical study as described under 21 C.F.R. §312.21(c) with respect to the United States, or, with respect to a jurisdiction other than the United States, a similar clinical study. [\*\*\*].
- **1.110** "Phase IV/Post-Approval Clinical Study" means any Post-Approval Optional Study or Post-Approval Required Study.

19

- **1.111** "Post-Approval Optional Study" means any a human clinical study initiated after receipt of Regulatory Approval for a Licensed Product with respect to any Indication for which Regulatory Approval in a country has been received, including an epidemiological study, modeling and pharmacoeconomic study, Investigator Sponsored Clinical Study or post-marketing surveillance study of a Licensed Product, in each case that is not intended for use as a basis for obtaining Regulatory Approval (*e.g.*, for a further indication, label expansion or otherwise) with respect to such Licensed Product and is not a Post-Approval Required Study.
- <u>1.112</u> "Post-Approval Required Study" means a human clinical or nonclinical study or registry initiated after receipt of Regulatory Approval for a Licensed Product with respect to any Indication for which Regulatory Approval in a country has been received and that is either recommended or required by a Regulatory Authority in such country, or agreed with a Regulatory Authority to be conducted, in each case, as a condition of receiving or maintaining such Regulatory Approval for such country.
- <u>1.113</u> "Private Health Care Plans" means non-governmental Third Party health care payors and plans, including insurance companies, health maintenance organizations and other managed care organizations, Blue Cross and Blue Shield plans and self-funded employers.
  - 1.114 "Prior CDA" means [\*\*\*].
- <u>1.115</u> "Product Liability Costs" means Out-of-Pocket Costs and FTE Costs incurred directly in connection with Third Party Product Liability Actions resulting from the Development, Manufacture or Commercialization of the Licensed Product pursuant to this Agreement.
  - 1.116 "Product Patent" means any [\*\*\*].
- <u>1.117</u> "**Product Related Materials**" means Promotional Materials, Product Training Materials, Medical Affairs Training Materials, and Medical Affairs Materials.
- **1.118** "**Product Trademark(s)**" means any trademark(s) and service mark(s) as may be approved in accordance with Section 8.7.2 for use in connection with the distribution, marketing, promotion and sale of a Licensed Product in the Field anywhere in the world, or accompanying logos, trade dress or indicia of origin.
  - **1.119** "**Progranulin**" means [\*\*\*].
- **1.120** "Regulatory Approval" means any approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in a country, including the expansion or modification of the label for additional Indications or uses, excluding pricing or reimbursement approvals.
- **1.121 "Regulatory Authority"** means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the

marketing and sale of a pharmaceutical product in a country, including FDA in the United States and EMA in the EU.

- **1.122** "**Regulatory Exclusivity**" means, with respect to a Licensed Product in a country, any exclusive marketing right, data protection, or other exclusive right, other than a Patent, conferred by any Governmental Authority with respect to such Licensed Product in such country, including any new drug exclusivity, new indication or use exclusivity, pediatric exclusivity, or orphan drug exclusivity.
- <u>1.123</u> "Regulatory Filing" means any filing or application with any Regulatory Authority with respect to a Licensed Antibody or Licensed Product, or its use or potential use in humans, including any documents submitted to any Regulatory Authority and all supporting Data and documentation related thereto, including INDs and MAAs, and all correspondence with any Regulatory Authority with respect to any Licensed Antibody or Licensed Product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).
  - **1.124** "**Relevant Internal Policies**" means, with respect to a Party, [\*\*\*].
- **1.125** "Royalty Term" shall mean, on a Licensed Product-by-Licensed Product and country-by-country basis, the period starting on the First Commercial Sale of the Licensed Product and ending on the latest to occur of: (a) [\*\*\*] ([\*\*\*]) [\*\*\*] from First Commercial Sale of such Licensed Product in such country, provided however such period shall continue on a Co-Funded Indication-by- Co-Funded Indication basis until [\*\*\*] ([\*\*\*]) [\*\*\*] after the First Commercial Sale of such Licensed Product for such Co-Funded Indication in such country; (b) the expiration of the last-to-expire Valid Claim of an Alector Patent, Joint Patent, Collaboration Patent or GSK PTE Patent Covering the Licensed Product in such country (as further described in the next sentence, the "Royalty Term Patents"); and (c) [\*\*\*]. [\*\*\*] For such purposes, a "Co-Funded Indication" means [\*\*\*].
  - 1.126 "Segregate" means, with respect to a product or program, [\*\*\*].
  - 1.127 "SORT1" means [\*\*\*].
- **1.128** "Standard Contractual Clauses" means the Standard Contractual Clauses (Controller to Controller) as set out in Commission Decision of 27 December 2004 amending Decision 2001/497/EC as amended, updated or replaced from time to time (or such other standard data protection clauses as may be adopted or approved by the UK Government or European Commission):
- **1.129** "**Subcontractor**" means a Third Party that is performing activities under this Agreement on behalf of a Party pursuant to a written agreement (such agreement, a "**Subcontract**").
  - 1.130 "Sublicensee" means a Person, other than an Affiliate or a distributor, that is granted

21

(directly or indirectly) rights to Develop or Commercialize a Licensed Antibody or Licensed Product [\*\*\*].

- **1.131 "Territory"** means the United States and the OUS Territory.
- **1.132 "Third Party"** means any Person other than a Party or any of its Affiliates.
- 1.133 "United States" or "U.S." means the United States of America and its territories and possessions.
- **1.134** "U.S. Commercialization Budget" means the [\*\*\*] [\*\*\*] rolling budget for conducting Commercialization of the Cost Profit Sharing Products in the United States pursuant to the U.S. Commercialization Plan during a given Calendar Year and the [\*\*\*] Calendar Years, as developed by the JCC and approved by the JSC in accordance with Section 5.3.3, which budget shall be updated and amended concurrently with the U.S. Commercialization Plan in accordance with Section 5.3.5(b).
- <u>1.135</u> "U.S. Commercialization Plan" means the commercialization plan with respect to the Commercialization of the Cost Profit Sharing Products in the Field in the United States during a given Calendar Year and the [\*\*\*] [\*\*\*], as developed by the JCC in accordance with Section 5.3.2, including the U.S. Commercialization Budget and annual Net Sales forecasts for the United States, as amended from time to time in accordance with the procedures set forth in this Agreement.
- 1.136 "Valid Claim" means a claim (i) of any issued, unexpired patent that has not been withdrawn, lapsed, abandoned, revoked, cancelled, disclaimed or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (ii) of any patent application that has not been cancelled, withdrawn, abandoned (without the possibility of refiling) or finally rejected by the applicable patent authority or court without the possibility of appeal but, if a claim of a pending patent application has not issued [\*\*\*] after the earliest filing date from which such claim takes priority, then such claim will cease to constitute a Valid Claim for the purposes of this Agreement unless and until such claim issues.

**1.137 Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>Definition</u>	<u>Section</u>
"1974 Convention"	14.3
[***]	[***]
"Acquirer"	14.2.1
[***]	[***]

22

"ADA Approval Milestone"	4.2.6(d)
"ADA Approval Percentage"	4.2.6(d)
"ADA Cost Percentage"	4.2.6(b)
"ADA Data Use"	4.2.6(a)
"ADA Data Use Date"	4.2.6(a)
"ADA Phase III Milestone"	4.2.6(c)
"Additional Know-How Transfer Plans"	3.3.2
[***]	[***]
[***]	[***]
"Agreement Wind-Down Period"	12.6.12
"Alector Change of Control"	14.2.5
[***]	[***]
"Alector Indemnified Parties"	11.2
"Alector Independent Know-How"	4.6.1(a)
"Alector Independent Patents"	4.6.1(b)
"Alector Independent Technology"	4.6.1(c)
"Alector Opt Out Date"	4.5.5
"Alector Opt Out"	4.5.5
[***]	[***]
[***]	[***]
"Alector Sole Inventions"	8.1.1
"Alector Wholly-Owned Affiliates"	3.4.2
"Alector's Co-Promote Right"	5.8.1
"Alliance Manager"	2.11
[***]	[***]
[***]	[***]
"Anticipated Excess Costs"	4.5.4(c)(i)
"Anti-Corruption Laws"	10.10.1(a)
"Approval Milestone"	7.2.2
"Approved CMO"	6.1.3(b)
"Bankruptcy Code"	3.8
"Biosimilar Application"	8.3.3
[***]	[***]
[***]	[***]
"Breaching Party"	12.2.1
[***]	[***]
"Buy Out Payment"	7.8
"CAPA"	4.4.5
"Claim"	11.4.1
"Clinical Study Milestone"	7.2.1
"Clinical/Regulatory Working Group"	2.6.2

<sup>\*\*\*</sup> Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

[***]	[***]
[***]	[***]
"Co-Funded Indication"	1.124
[***]	[***]
"Collaboration Losses"	Exhibit 1.51
"Collaboration Patents"	1.21
"Commercial Milestone"	7.2.3
"Committed Opt Out Cost Share Studies"	4.5.5(b)(iii)
[***]	[***]
[***]	[***]
"Confidential Information"	9.1
"Convicted Entity"	10.9.1(d)
"Convicted Individual"	10.9.1(d)
"Cooperating Party"	9.4.2
"Co-Promoting Party"	5.8.1
[***]	[***]
[***]	[***]
[***]	[***]
"Currency Gains and Losses"	7.14.2
"Debarred Entity"	10.9.1(b)
"Debarred Individual"	10.9.1(a)
[***]	[***]
"Development Reconciliation Procedures"	4.5.3
"Dispute"	13.4.1
[***]	[***]
[***]	[***]
"DMF"	4.4.4
"DOJ"	14.16
[***]	[***]
"Entity"	7.12.1
[***]	[***]
"Excluded Entity"	10.9.1(c)
"Excluded Individual"	10.9.1(c)
"Existing Manufacturing Contracts"	6.1.2(e)
"Existing Third Party Agreement Payments"	7.8
"Expert Dispute"	13.3.1(a)
"Expert Resolution Notice"	13.3.1(a)
"Expert"	13.3.2(b)
"Field Based Representative"	5.16.1
[***]	[***]
"Finance Working Group"	2.6.1

<sup>\*\*\*</sup> Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

"Financial Report"	7.6.2
[***]	[***]
"FTC"	14.16
"Gene Therapy Addendum"	4.8.1(a)
"Gene Therapy GDP"	4.8.1(a)
"Gene Therapy Opt-In Notice"	4.8.1
"Gene Therapy Opt-In Notice Date"	4.8.1
"Gene Therapy Proposal"	4.8.1
"Global Publication Strategy"	9.5.1
"Global Regulatory Strategy"	2.6.2
"Global Strategic Launch Plan"	5.3.1
"GSK Indemnified Parties"	11.1
"GSK Independent Know-How"	4.6.1(d)
"GSK Independent Patents"	4.6.1(e)
"GSK Independent Technology"	4.6.1(f)
[***]	[***]
[***]	[***]
"GSK Sole Inventions"	8.1.1
"GSK Wholly-Owned Affiliates"	3.4.1
[***]	[***]
[***]	[***]
"HSR Act"	14.16
"HSR Clearance Date"	14.16
"ICC Arbitration Rules"	13.3.2(b)
"ICC"	13.3.2(b)
"Incremental Royalty"	7.4.2(b)(ii)
"Incumbent Board"	14.2.5
"Indemnified Party"	11.4.1
"Indemnifying Party"	11.4.1
"Independent ADA"	4.2.6(a)
"Independent Technology"	4.6.1(g)
"Indirect Taxes"	7.11
"Infringement Claim"	8.5
[***]	[***]
"Initial Alector Know-How Transfer Plan"	3.3.1
"Initial Alector Patents"	1.8
"Initial GDP"	1.58
"Initial Manufacturing Period"	6.1.2(b)
[***]	[***]
[***]	[***]
"JCC"	2.5.1

"JCOWG"	2.6.4
"JDC"	2.2.1
"JMC"	2.3
"Joint Committee"	2.7
"Joint Inventions"	8.1.2
"JPC"	2.4
"JSC"	2.1.1
"Launched Products"	12.6.12
"Lead Party"	5.1.3(e)
[***]	[***]
"Losses"	11.1
"Major and Related Indications"	5.1.3(c)(i)
"Manufacturing Party"	6.4
"Manufacturing Subcontract"	6.1.3
"Manufacturing Subcontractor"	6.1.3(d)
"Manufacturing Transfer Plan"	6.2
"Manufacturing Transfer"	6.2
[***]	[***]
"Material Manufacturing Subcontract"	6.1.3(b)
[***]	[***]
[***]	[***]
"MLR Working Group"	5.4.3
[***]	[***]
"New Product Decision"	4.6.1(h)
"Non-AD/PD Minor Indications"	5.1.3(c)(ii)
"Non-Breaching Party"	12.2.1
[***]	[***]
"Non-Manufacturing Party"	6.4
"Offending Activities"	5.1.3(d)
[***]	[***]
[***]	[***]
"On-Going Clinical Study"	12.6.11
"Opt Out Commercialization Plan"	5.3.4
"Opt Out Notice Date"	4.5.5
"Opt Out Product"	4.5.5
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
"Oversight/Quality Working Group"	4.3.6

[***]	[***]
"Patient Samples"	4.7.1
"Payee"	7.10.2
"Payor"	7.10.2
[***]	[***]
"Pharmacovigilance Agreement"	5.12.1
"Phase III and Later Development Costs"	7.4.2(b)(i)
[***]	[***]
[***]	[***]
"PHSA"	8.3.3
"PRC Working Group"	5.5.1
"Preferred Development Subcontractor List"	4.3.2(a)
"Product Materials"	Exhibit 1.51
"Product Trademark Costs"	8.7.2
"Progranulin Gene Therapy"	4.8.2
"Promotional Materials"	5.5.1
"Proposed Publications"	9.5.2
"Prosecution"	8.2.1
"Publishing Party"	9.5.2
[***]	[***]
"Reconciliation Procedures"	7.6.1
[***]	[***]
"Requesting Party"	9.4.2
"Reversion Royalty Term"	12.6.6
"Reverted Know-How"	12.6.4
"Reverted Licensed Antibodies"	12.6.5(a)
"Reverted Products"	12.6.5(a)
"Reviewing Party"	9.5.2
"Royalty Term Patents"	1.124
"Safety Review Working Group"	2.6.3
"Sales Representative"	5.16.1
[***]	[***]
[***]	[***]
"Selling Entity"	1.96
"Severed Clause"	14.5
"Shared Product Liability Costs"	11.3
[***]	[***]
"Sole Inventions"	8.1.1
"Subcontract"	1.129
"Sublicense"	3.4.3
"Supply and Quality Agreement"	6.4

[***]	[***]
[***]	[***]
"Tax Action"	7.10.3
"Tax"	7.10.5
"Taxes"	7.10.5
"Termination Notice"	12.2.1
[***]	[***]
"Third Party Product Liability Action"	11.5.1
"Tracking Records"	4.7.5
"True-Up Payment"	7.2.5(b)
"UK DPA"	1.43
[***]	[***]
"Working Group"	2.6

# ARTICLE II MANAGEMENT OF COLLABORATIVE ACTIVITIES

## **2.1** <u>Joint Steering Committee</u>.

**2.1.1** Formation; Purposes and Principles. Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint steering committee (the "JSC"), comprised of senior executives, to provide high-level oversight and certain decision-making regarding the activities of the Parties under this Agreement. The JSC will not be involved in day-to-day implementation of activities under this Agreement. The purposes of the JSC shall be (i) to review and oversee the overall global Development, Manufacture and U.S. Commercialization of the Cost Profit Sharing Products in the Field pursuant to this Agreement and (ii) to oversee the JDC, JMC, JPC, JCC and Finance Working Group and resolve matters on which the JDC, JMC, JPC, JCC or Finance Working Group are unable to reach unanimous agreement, except as otherwise provided herein. In conducting its activities, the JSC shall operate and make its decisions consistent with the terms of this Agreement.

#### **2.1.2** <u>Responsibilities</u>. The JSC shall have responsibility for the following activities:

- (a) review and approve substantive amendments and updates to the GDP presented by the JDC, including the Development Budget;
- (b) review and approve the Global Regulatory Strategy (and substantive amendments and updates thereto) included in the GDP;
- (c) review and approve the Manufacturing Transfer Plan, including amendments thereto presented to the JSC by the JMC;

28

presented to the J	(d)_review and approve the Initial Alector Know-How Transfer Plan, including amendments thereto SC by the JDC:
presented to the s	
the JCC;	(e)_review and approve the initial U.S. Commercialization Plan, [***] in each case presented to the JSC by
thereto;	(f) review and discuss the initial Global Strategic Launch Plan and any substantive amendments and updates
	(g)_review and approve the Global Publication Strategy (and substantive amendments and updates thereto);

(i) [\*\*\*]; and

(j)\_perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement as agreed in writing by the Parties, including periodic evaluations of performance against goals.

(h) review and approve the Compliance Program and any modification or update thereof [\*\*\*];

### 2.2 Joint Development Committee.

**2.2.1** Formation; Purposes. Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint development committee (the "JDC"), which shall report to the JSC and have responsibility for (i) providing oversight to various Working Groups that report to the JDC, (ii) monitoring and facilitating the overall progress of Development activities under this Agreement with respect to Licensed Products in the Field, including oversight of the various budgets and activities, (iii) overseeing the implementation of all Development operational aspects of the collaboration established by this Agreement, and (iv) forming additional Working Group(s) from time to time and delegating to such Working Group(s) such operational responsibilities as the JDC may determine necessary or desirable. In conducting its activities, including in the allocation of activities to the Parties under the GDP, the JDC shall operate and make its decisions consistent with the terms of this Agreement.

## **2.2.2** <u>Specific Responsibilities</u>. In particular, the JDC shall:

- (a) in conjunction with the JPC, oversee and coordinate the sharing and transfer of Know-How and Materials pursuant to Sections 3.3.1 and 3.3.3;
  - (b) oversee the implementation of the GDP [\*\*\*];
- (c) review and update the GDP, including the Development Budget set forth therein and the allocation of Development responsibilities between the Parties (including [\*\*\*]),

29

on an annual basis and, from time to time, present to the JSC for review and approval proposed substantive amendments to the GDP, including the Development Budget, in accordance with Section 4.2.5;

- (d) review and discuss the Non-Core GDP on an annual basis;
- (e) review and discuss material activities conducted under the Non-Core GDP;
- (f) oversee the implementation of the Global Regulatory Strategy for the Regulatory Approval of the Cost Profit Sharing Products once it has been approved by the JSC;
- (g) perform the responsibilities of the Clinical/Regulatory Working Group as set forth in Section 2.6.2 if the Clinical/Regulatory Working Group does not exist;
  - (h) [\*\*\*];
- (i) perform the responsibilities of the Safety Review Working Group as set forth in Section 2.6.3 if the Safety Review Working Group does not exist;
  - (j) review and approve any New Product Decision;
  - (k) [\*\*\*];
  - (l) [\*\*\*];
- (m) review, approve and update the Global Publication Strategy on at least a [\*\*\*] basis and present to the JSC for approval, proposed substantive amendments to the Global Publication Strategy in accordance with Section 9.5.1;
  - (n) review and evaluate results from Clinical Studies; and
- (o) perform such other functions as are assigned to it in this Agreement or as are appropriate to further the purposes of this Agreement as agreed in writing by the Parties.

#### 2.3 Joint Manufacturing Committee.

Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint manufacturing committee (the "**JMC**"), which shall report to the JSC and shall have responsibility for overseeing the implementation of all Manufacturing aspects of the collaboration established by this Agreement, [\*\*\*]. Until formal establishment of the JMC, appropriate representatives from the Parties' (or their Affiliates') manufacturing and quality functions shall perform the functions of the JMC. In conducting its activities, the JMC shall operate and make its decisions consistent with the terms of this Agreement.

30

## 2.4 Joint Patent Committee.

Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint patent committee (the "JPC"), which shall have responsibility for (i) coordinating and facilitating communications and the Parties' conduct of activities under this Agreement regarding [\*\*\*] as contemplated under Sections 8.1, 8.2, 8.3, 8.4, and 8.6; (ii) coordinating on a consistent strategy for the prosecution of [\*\*\*]; (iii) [\*\*\*]; and (iv) coordinating with the other committees regarding the foregoing matters and such other patent-related matters as may arise from time to time. Until formal establishment of the JPC, appropriate representatives from the Parties' (or their Affiliates') intellectual property functions shall perform such functions.

#### 2.5 Joint Commercialization Committee.

**2.5.1** Formation; Purposes. No later than [\*\*\*] [\*\*\*] prior to the anticipated First Commercial Sale of a Licensed Product, Alector and GSK shall establish a joint commercialization committee (the "JCC"), which shall report to the JSC and have responsibility for (i) overseeing the Commercialization of Cost Profit Sharing Products in the U.S., (ii) providing a forum for exchanging information regarding the Commercialization of Licensed Products [\*\*\*], and (iii) forming Working Group(s) from time to time and delegating to such Working Group(s) such operational responsibilities as the JCC may from time to time determine necessary or desirable. The JCC shall include [\*\*\*] from both Alector and GSK to advise the JCC on compliance with relevant Laws and policies. In conducting its activities, the JCC shall operate and make its decisions consistent with the terms of this Agreement.

## **2.5.2** Specific Responsibilities. In particular, the JCC shall:

- (a)\_review and present to the JSC for approval the U.S. Commercialization Plan, including the U.S. Commercialization Budget, in accordance with Sections 5.3.2 and 5.3.3;
- (b)\_review and update the U.S. Commercialization Plan, including the U.S. Commercialization Budget set forth therein and the allocation of responsibilities between the Parties, on an annual basis (or at such other frequency as the Parties agree) and, from time to time, present to the JSC for review and approval proposed updates and substantive amendments to the U.S. Commercialization Plan, including the U.S. Commercialization Budget, in accordance with Section 5.3.5(b);
- (c)\_oversee the implementation of the U.S. Commercialization Plan within the U.S. Commercialization Budget once it has been approved by the JSC;
- (d)\_provide a forum for discussion and exchange of information with respect to the Commercialization of Licensed Products [\*\*\*];

31

- (e) review and discussion of the Compliance Program, as described in Exhibit 5.17.1;
- (f) review and approve the Product Trademarks from a shortlist of marks proposed by GSK;
- (g)\_share planning and budgeting information with the JDC and coordinate with the JDC [\*\*\*], as applicable, to the JSC;
  - (<u>h</u>)[\*\*\*]; and
- (i)\_perform such other functions as are assigned to it in this Agreement or as are appropriate to further the purposes of this Agreement as agreed in writing by the Parties.

## 2.6 Working Groups.

From time to time, the JSC, JDC and JCC may establish various working groups (each, a "**Working Group**") to oversee particular projects or activities, including those Working Groups described below in this Section 2.6, and each such Working Group shall be constituted and shall operate as the JSC, JDC or JCC determines.

- **2.6.1** Finance Working Group. Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint Finance Working Group (the "Finance Working Group"), which shall report to the JDC with respect to the Development of the Licensed Products, to the JCC with respect to the Commercialization of the Licensed Products and to the JSC with respect to the Pre-Tax Profit or Loss and royalty statements in accordance with the Reconciliation Procedures and the Financial Exhibit, and operate in coordination with the various committees and Working Groups. The Finance Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting. The Finance Working Group shall be responsible for:
- (a) coordinating and conducting the accounting, reporting, reconciliation and other related activities set forth in this Agreement and the Financial Exhibit,
- (b) advising and provide support to the JSC and the other committees with respect to financial, accounting, budgeting, reporting and other issues that may arise in connection with the various plans and corresponding budgets for activities thereunder;
- (c) reviewing Development Costs, including relevant FTE Costs, Out-of-Pocket Costs and Supply Costs, incurred by the Parties and their Affiliates hereunder;
  - (d) recommending for approval by the JSC any changes to reporting procedures;

32

- (e) coordinating [\*\*\*];
- (f) performing and reviewing [\*\*\*];
- (g) coordinating audits pursuant to Section 7.9, by Third Party audit firms, and discussing and attempting to resolve discrepancies or issues arising from such audits;
  - (h) facilitating review of financial aspects of press releases pursuant to Section 9.4.2;
- (i) performing such other functions as are specifically designated to the Finance Working Group in this Agreement or the Financial Exhibit, or as the Parties otherwise agree are appropriate to further the purposes of this Agreement;
- (j) working with the JSC and the committees to assist in financial, budgeting and planning matters, and providing periodic updates to the JSC, JDC, JMC and JCC on financial matters relating to this Agreement, and perform such other financial matters as are delegated to it under this Agreement or by the JSC, JDC, JMC and JCC; and
  - (k) making such decisions and determinations as are assigned to it under this Agreement.
- **2.6.2** Clinical/Regulatory Working Group. Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK will establish a joint clinical/regulatory Working Group (the "Clinical/Regulatory Working Group") which shall report to the JDC and that will consist of appropriately selected delegates from both Parties and have responsibility for (i) establishing a global regulatory strategy for the Cost Profit Sharing Products and ensure consistency across the Regulatory Filings for Cost Profit Sharing Products and responses to Regulatory Authorities in connection with Licensed Products, to the extent possible (such strategy, the "Global Regulatory Strategy"); (ii) providing a forum for the Parties to review and discuss regulatory matters as provided in Section 4.4; (iii) [\*\*\*], and (iv) review and approve the protocol for each Clinical Study with respect to Cost Profit Sharing Products. Until formal establishment of a Clinical/Regulatory Working Group, appropriate representatives from the Parties' (or their Affiliates') clinical/regulatory groups shall perform the functions of the Clinical/Regulatory Working Group.
- **2.6.3** <u>Safety Review Working Group</u>. Within [\*\*\*] after the Effective Date, Alector and GSK will establish a joint Safety Review Working Group (the "**Safety Review Working Group**") that shall report to the JDC and that will consist of appropriately selected delegates from both Parties. The Safety Review Working Group shall discuss and implement processes and procedures, including under the Pharmacovigilance Agreement, for sharing information needed to support each Party's (or their Affiliates') respective regulatory responsibilities and which may be necessary for compliance with the applicable regulatory pharmacovigilance requirements. Any such procedures shall not be construed to restrict either Party's ability to take any action that it

deems appropriate or required of it under the applicable regulatory requirements, but when permitted by applicable Laws the Parties shall consult with each other before taking such action. Notwithstanding the foregoing, substantive discussions relating to safety (including safety signals and pharmacovigilance matters) shall be discussed at the [\*\*\*]. [\*\*\*].

**2.6.4** <u>Joint Compliance Oversight Working Group</u>. Within [\*\*\*] [\*\*\*] after the Effective Date, Alector and GSK shall establish a joint compliance oversight working group (the "**JCOWG**"), which shall report to the JSC and shall have responsibility for establishing and overseeing the implementation of the Compliance Program, [\*\*\*]. The JCOWG shall have the right to establish as Working Groups reporting to it, one or more MLR Working Groups [\*\*\*].

### 2.7 Membership.

Each of the JSC, JDC, JMC, JPC and JCC shall be composed of an equal number of representatives appointed by each of Alector and GSK. The JSC shall be comprised of [\*\*\*] ([\*\*\*]) representatives of each Party. The JDC, JMC, and JCC shall each be comprised of at least [\*\*\*] ([\*\*\*]) but no more than [\*\*\*] ([\*\*\*]) representatives of each Party, as determined by the JSC. The JPC shall be initially comprised of [\*\*\*] ([\*\*\*]) representatives of each Party, except as otherwise determined by the JSC. Each Party shall have the right to appoint any number of representatives to the various Working Groups. Each Party may replace JSC, JDC, JMC, JPC, JCC and any Working Group representatives at any time upon written notice to the other Party, provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. Each Party's representatives to each Joint Committee shall be individuals suitable in seniority and experience and amongst such representatives shall be at least one representative from each Party with relevant decision-making authority to make decisions within the scope of the applicable Joint Committee's responsibilities, provided that it is understood that such individual may need to seek appropriate authority from the relevant Party with respect to certain matters. The JSC, JDC, JMC, JPC, JCC and the various Working Groups (each, a "Joint Committee") shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Joint Committee shall not have any greater authority than any other representative on the committee or Working Group. The co-chairpersons shall be responsible for (i) calling meetings; (ii) preparing (with the assistance of the Alliance Managers) and circulating an agenda in advance of each meeting, provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (iii) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement (for clarity in accordance with ARTICLE VIII with respect to the JPC); and (iv) preparing and issuing minutes of each meeting within [\*\*\*] [\*\*\*] thereafter. For the avoidance of doubt, each Party may designate the same individual as a representative on more than one Joint Committee, and each Party may designate contractors or employees of its Affiliates as its representatives (including cochairperson) on the Joint Committee.

#### 2.8 Decision-Making.

34

- **2.8.1** <u>Voting</u>. Each Joint Committee shall operate by unanimous agreement; provided, however, that the JPC shall operate in accordance with the provisions of ARTICLE VIII, rather than by unanimous agreement. With respect to decisions of each Joint Committee, the representatives of each Party shall have collectively one vote on behalf of such Party. Except as otherwise expressly set forth in this Agreement, use of the phrases "determine," "establish," "delegate," "approve," "develop," "update," "submit," "prepare," "resolve," or "determine whether to approve" (including any conjugates thereof) by the Joint Committees, will mean that the decision making provisions of this Section 2.8 apply to such matter, including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified to be "recommended", "advised", "overseen", "managed," "reviewed," "discussed," "monitored," "provided a forum," "performed," "facilitated," "coordinated," "cooperated," or "shared" (including any conjugates thereof) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 2.8.
- **2.8.2** <u>Joint Committee Escalation</u>. Should the members of any Working Group (other than the JPC) maintain their disagreement for more than [\*\*\*] ([\*\*\*]) [\*\*\*] on any matter that is within its authority under this Agreement for which unanimous agreement is required and has been sought and Alector or GSK requests a resolution, the matter shall be referred to the Joint Committee to which such Working Group reports for discussion and resolution. Should the members of the JDC, JMC or JCC maintain any disagreement for more than [\*\*\*] ([\*\*\*]) [\*\*\*] on any matter that is within its authority under this Agreement for which unanimous agreement has been sought and Alector or GSK requests a resolution, the matter shall be referred to the JSC for resolution. Should the members of the JSC maintain their disagreement for more than [\*\*\*] ([\*\*\*]) [\*\*\*], either with respect to any matter referred to it by the JDC, JMC or JCC, or with respect to a matter initially arising within the JSC, such matter shall be resolved pursuant to Sections 13.1 and 13.3, subject to Section 2.8.3.
- **2.8.3** Limitations on Joint Committee Authority. Neither Party shall have the right to exercise its deciding vote with respect to a decision within the authority of a Joint Committee as contemplated under Sections 2.10 or 13.3.1 to do any of the following: (a) finally determine any interpretation of this Agreement or the Parties' rights or obligations hereunder, (b) conflict with any terms and conditions of this Agreement, (c) be in contravention of applicable Law in any respect; or (d) to otherwise expand or reduce the other Party's rights or obligations under this Agreement or materially increase the other Party's or its Affiliates' or Sublicensees' costs or expenses under this Agreement (including, for example, by committing additional financial or other resources of the other Party to any Clinical Study as compared to the then last GDP approved by the other Party (either itself or through its representatives on the JSC or Executive Officers pursuant to Section 13.1)). For the avoidance of doubt, disputes arising between the Parties in connection with or relating to this Agreement, or any document or instrument delivered in connection herewith, in each case, that are outside of the decision-making authority of the Joint Committees and not within a Party's sole decision-making authority hereunder, shall be resolved pursuant to Section 13.4. Each Party shall retain the rights, powers and discretion granted to it

35

under this Agreement and no such rights, powers or discretion shall be delegated to or vested in a Joint Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. No Joint Committee shall have the power to, and no deciding vote of a Party on a matter referred to such Person shall, amend, modify or waive compliance with this Agreement, which compliance may only be amended or modified as provided in Section 14.7 or compliance with which may only be waived as provided in Section 14.7. [\*\*\*].

#### 2.9 Meetings of the JSC, JDC, JMC, JPC, JCC and Working Groups.

The JSC shall hold meetings at such times as the JSC shall determine, and the JDC, JMC, JPC and JCC shall hold meetings at such times as the applicable committee determines (or as directed by the JSC), but in no event shall such meetings of the JSC, JDC, JMC, JPC and JCC be held less frequently than [\*\*\*] every Calendar Year during the Term for so long as each such committee exists. Each Working Group shall hold meetings at such times as the Working Group agrees, or as the JDC, JMC, JPC, JCC or the JSC directs. Each of the Joint Committees may meet in person or by audio or video conference as the Parties may mutually agree. With respect to in-person meetings of a Joint Committee, the representatives shall meet alternately at a location(s) designated by Alector and GSK. Each Party shall be responsible for its own costs and expenses in attending Joint Committee meetings and, for clarity, such costs and expenses shall not be included in Allowable Expenses for purposes of calculating Pre-Tax Profit or Loss in accordance with the Financial Exhibit, Development Costs or Manufacturing Costs. Other representatives of the Parties, their Affiliates and Third Parties involved in the Development, Manufacture or Commercialization of the Licensed Products may attend such meetings of a Joint Committee as nonvoting observers. Any Joint Committee may upon agreement meet on an ad hoc basis between regularly scheduled meetings in order to address and resolve time-sensitive issues within their purview that may arise from time to time. No action taken at a meeting of a Joint Committee shall be effective unless a representative of each Party is present or participating. Neither Party shall unreasonably withhold attendance of at least [\*\*\*] representative of such Party at any meeting of a Joint Committee for which reasonable advance notice was provided.

2.10 [\*\*\*]

#### 2.11 Alliance Managers.

Each Party shall designate a single alliance manager for all of the activities contemplated under this Agreement ("Alliance Manager"). Such Alliance Managers will be responsible for the day-to-day worldwide coordination of the collaboration contemplated by this Agreement and will serve to facilitate communication between the Parties. Such Alliance Managers shall have experience and knowledge appropriate for managers with such project management responsibilities. The Alliance Managers shall attend the JSC meetings (or designate an appropriate representative to attend JSC meetings on such Alliance Manager's behalf). The Alliance Managers shall not be counted as members of any Joint Committee (and shall not vote on matters discussed at any Joint

36

Committee meeting). Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.

# ARTICLE III LICENSE GRANTS

#### 3.1 Alector Grants.

- **3.1.1** <u>Development License</u>. Subject to the terms and conditions of this Agreement (including Section 4.6), Alector hereby grants to GSK an exclusive (subject to Alector's reserved rights under Section 3.9.1), worldwide, sublicenseable (in accordance with Section 3.4) license under the Alector Intellectual Property to Develop the Licensed Antibodies and Licensed Products in the Field in the Territory.
- **3.1.2** <u>Manufacturing License</u>. Subject to the terms and conditions of this Agreement, Alector hereby grants to GSK an exclusive (subject to Alector's reserved rights under Section 3.9.1), worldwide, sublicenseable (in accordance with Section 3.4) license under the Alector Intellectual Property to Manufacture the Licensed Antibodies and Licensed Products in the Field in the Territory.

#### 3.1.3 Commercialization License.

- (a) *United States*. Subject to the terms and conditions of this Agreement, Alector hereby grants to GSK (i) an exclusive (subject to Alector's reserved rights under Section 3.9.1), worldwide, sublicenseable (in accordance with Section 3.4) license under the Alector Intellectual Property to Commercialize the Cost Profit Sharing Products in the Field in the United States and (ii) an exclusive license under the Alector Intellectual Property to Commercialize the Opt Out Products in the United States.
- (b) *OUS Territory*. Subject to the terms and conditions of this Agreement, Alector hereby grants to GSK an exclusive license (subject to Alector's reserved rights under Section 3.9.1) under the Alector Intellectual Property to Commercialize the Licensed Products in the Field in the OUS Territory; provided that Alector shall retain the right to perform such activities (if any) to the extent allocated to Alector under the Global Strategic Launch Plan or requested by GSK or its Affiliate.

#### 3.2 GSK Grants.

**3.2.1** <u>Development License</u>. Subject to the terms and conditions of this Agreement (including Section 4.6), GSK hereby grants to Alector a non-exclusive license under the GSK Intellectual Property to Develop the Cost Profit Sharing Products in the Field in the Territory.

3.2.2 [\*\*\*]

37

#### 3.3 Sharing of Data and Know-How and Materials.

- **3.3.1** <u>Initial Transfer.</u> As soon as reasonably practicable after the Effective Date, and in any event within [\*\*\*] ([\*\*\*]) [\*\*\*] after the formation of the JDC, the Parties shall discuss in good faith and agree upon, and, following such agreement, shall perform their respective obligations set out in, a technology and data transfer plan (the "**Initial Alector Know-How Transfer Plan**") governing the contents and mechanics of the transfer to GSK of the Alector Know-How and Materials existing as of the date of such transfer [\*\*\*]. The Initial Alector Know-How Transfer Plan shall be prepared by the JDC for approval by the JSC within [\*\*\*] ([\*\*\*]) [\*\*\*] after the formation of the JDC, and may be amended from time to time as prepared by the JDC and approved by the JSC. Notwithstanding the foregoing, for no additional consideration (including no reimbursement for any costs or expenses incurred by or on behalf of Alector), Alector shall provide the following items to GSK in a format (excel, word, powerpoint, etc.) and a method agreed to by the Parties (to the extent not specified below):
- (a) within [\*\*\*] ([\*\*\*]) [\*\*\*] following the Effective Date, download access to the complete contents of the diligence data room hosted by Alector for GSK's review of the Licensed Antibodies and Licensed Products;
- (b) within [\*\*\*] ([\*\*\*]) [\*\*\*] after the formation of the JDC, copies of the following (including all eCTD sequences and source documents (if any) comprising or containing any of the following) to the extent not already provided: [\*\*\*].
- in each case (a) and (b) that are: (i) Alector Know-How or Materials with respect to the Existing Antibodies or Existing Products, (ii) [\*\*\*] (iii) [\*\*\*]. Following the date of the foregoing transfer, upon GSK's reasonable request, Alector shall in good faith make its relevant scientific and technical personnel reasonably available to GSK to answer questions or provide information or instruction concerning the Alector Know-How and Materials in order to better enable GSK's personnel to utilize the Alector Know-How and Materials in the Development and Commercialization of the Licensed Antibodies and Licensed Products in accordance with the GDP.
- 3.3.2 Additional Transfers. Pursuant to one or more technology and data transfer plans established by the JDC ("Additional Know-How Transfer Plans"), and in any event within a reasonable period of time following any reasonable and specific request from the other Party, each Party will transfer to the other Party copies [\*\*\*], in each case (a)-(c) that (i) [\*\*\*], in each case with respect to the Existing Antibodies or Existing Products or Licensed Antibodies or Licensed Products for which there has been an approved New Product Decision in accordance with Section 4.6, (ii) are in such Party's (or its Affiliates') possession and Control as of the relevant time, (iii) [\*\*\*] other Party to perform the Development activities allocated to such Party under ARTICLE IV of this Agreement and within the scope of the licenses granted under Section ARTICLE III [\*\*\*], and (iv) have not previously been provided to such other Party.
- **3.3.3** Sharing of Collaboration Data and Know-How. Without prejudice to Section 3.3.2, each Party shall (and shall cause its Affiliates to) reasonably cooperate with the other Party to

38

promptly share [\*\*\*], within the Collaboration Intellectual Property (other than with respect to Patient Samples, for which sharing and access shall be subject to the terms of Section 4.7 and provided that access to the GSK Manufacturing Know-How by a Third Party shall be limited to if and to the extent approved by GSK pursuant to Section 6.1.3(b)), and the JDC and JPC may establish reasonable policies to effectuate such exchange of Data and Know-How within the Collaboration Intellectual Property.

**3.3.4** General Tools. Notwithstanding the above in this Section 3.3 neither Party shall be obligated to provide or make available to the other Party discovery or research tools, materials or information (including screening assays, cloning tools, animal models, cell lines and the like) Controlled by such Party or its Affiliates that are generally applicable to the discovery or research of products for the treatment of diseases or conditions, except as mutually agreed by the Parties.

#### 3.4 Sublicensing.

- **3.4.1** <u>GSK Right to Sublicense</u>. In addition and without prejudice to any right to grant Subcontracts pursuant to Sections 4.3.2, 5.2.1 and 6.1.3, GSK shall have the right to grant sublicenses to its Affiliates [\*\*\*]. In the event that GSK grants any sublicense pursuant to this Section 3.4.1, GSK shall remain responsible for its obligations under this Agreement and shall be responsible for the performance of the relevant sublicensee during the Term, as if performed by GSK. In addition, GSK shall ensure that each of its sublicensees complies with all relevant provisions of this Agreement.
- **3.4.2** <u>Alector Right to Sublicense.</u> In addition and without prejudice to any right to grant Subcontracts pursuant to Sections 4.3.2, 5.2.1 and 6.1.3, Alector shall have the right to grant sublicenses to its Affiliates that are wholly-owned direct or indirect subsidiaries of Alector ("**Alector Wholly-Owned Affiliates**") of any and all rights granted to Alector under this Agreement by GSK (or to license rights retained by Alector), including any and all rights licensed to Alector pursuant to Section 3.2. Alector shall have the right to grant sublicenses to its Affiliates that are not Alector Wholly-Owned Affiliates and Third Parties of any and all rights granted to Alector under this Agreement by GSK (or to license rights retained by Alector) with respect to Licensed Antibodies and Licensed Products in the Field pursuant to Section 3.2 [\*\*\*], provided further that the right to sublicense or Subcontract any Manufacturing hereunder shall be subject to Section 6.1.3. In the event that Alector grants any sublicense pursuant to this Section 3.4.2, Alector shall remain responsible for its obligations under this Agreement during the Term and shall be responsible for the performance of the relevant sublicensee as if performed by Alector. In addition, Alector shall ensure that each of its sublicensees complies with all relevant provisions of this Agreement.
- **3.4.3** <u>Sublicense Requirements</u>. Each sublicense granted by a Party to a Third Party pursuant to Sections 3.4.1 or 3.4.2 (a "**Sublicense**") shall (i) be in writing; (ii) be subject and subordinate to, and consistent with, the terms and conditions of this Agreement; (iii) require the applicable Sublicensee to comply with all applicable terms of this Agreement (except for the

39

payment obligations, for which the sublicensing Party shall remain responsible); (iv) require that the Sublicensee grant the other Party a right of reference to the same extent of the right of reference granted to such other Party pursuant to Section 4.4.4 (unless plainly unnecessary because the nature of the applicable Sublicense does not relate to relevant subject matter); and (v) prohibit further sublicensing, except on terms consistent with this Section 3.4.3. No Sublicense shall diminish, reduce or eliminate any obligation of either Party under this Agreement. Upon reasonable request, the sublicensing Party shall provide the other Party with a copy of each Sublicense, provided that the sublicensing Party may redact any information from such Sublicense to the extent that such redactions do not reasonably impair the other Party's ability to ensure compliance with this Agreement.

**3.4.4** Existing Third Party Agreements. As of the Execution Date, Alector represents that neither Alector nor any of its Affiliates has entered into any material agreements with any Third Party relating to the Development, Manufacture or Commercialization of any Licensed Antibodies or Licensed Products, except those set forth in Exhibit 1.47.

#### 3.5 Alector Covenants.

Subject to Section 3.7, during the period beginning on the Execution Date and ending [\*\*\*], except pursuant to the terms of this Agreement, neither Alector nor any of its Affiliates shall [\*\*\*].

# 3.6 GSK Covenants.

Subject to Section 3.7, during the period beginning on the Execution Date and ending on [\*\*\*], except pursuant to the terms of this Agreement, neither GSK nor any of its Affiliates shall [\*\*\*].

3.7 [<u>\*\*\*</u>]

#### **3.8** Section 365(n) of the Bankruptcy Code.

All rights and licenses granted under or pursuant to any section of this Agreement, including Sections 3.1 and 3.2 hereof, are rights to "intellectual property" (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code")). Alector and GSK hereby acknowledge, on behalf of themselves and their respective Affiliates, that (i) copies of research data, (ii) laboratory samples, (iii) product samples and inventory, (iv) formulas, (v) laboratory notes and notebooks, (vi) all Data and results related to Clinical Studies, (vii) Regulatory Filings and Regulatory Approvals, (viii) rights of reference in respect of Regulatory Filings and Regulatory Approvals, (ix) pre-clinical research data and results, and (x) marketing, advertising and promotional materials, constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code. Each of Alector and GSK agree not to, and to cause their respective Affiliates not to, interfere with the other Party's or its Affiliate's exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agree to use Commercially Reasonable Efforts to assist the

40

other Party or its Affiliate to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary for the other Party or its Affiliate to exercise such rights and licenses in accordance with this Agreement.

#### **3.9** Retention of Rights.

- **3.9.1** By Alector. Except as expressly provided herein, Alector grants no other right or license, including any rights or licenses to the Alector Intellectual Property or any other intellectual property rights, whether by implication, estoppel or otherwise and GSK shall not use or otherwise exploit (or authorize the use or exploitation of) any Alector Intellectual Property (other than Joint Inventions and Joint Patents) except as provided in Section 3.1. Notwithstanding any provision to the contrary in this Agreement, Alector shall retain the right to (a) use and otherwise exploit the Alector Intellectual Property, including the right to grant and authorize licenses under such Alector Intellectual Property, for the purposes of conducting activities for which it is responsible as set forth in this Agreement and permitted under this Agreement, and (b) use and otherwise exploit the Alector Intellectual Property, including the right to grant and authorize licenses thereunder, for the following purposes: [\*\*\*].
- **3.9.2** By GSK. Except as expressly provided herein, GSK grants no other right or license, including any rights or licenses to the GSK Intellectual Property any other intellectual property rights not otherwise expressly granted herein, whether by implication, estoppel or otherwise and Alector shall not use or otherwise exploit (or authorize the use or exploitation of) any GSK Intellectual Property (other than Joint Inventions and Joint Patents) except as provided in Section 3.2.
- **3.9.3** Other Binding Moieties. Notwithstanding anything to the contrary in this Agreement, the Alector Intellectual Property and GSK Intellectual Property shall not include (a) any Know-How with respect to the binding portion(s) of an Antibody or other compound that is not directed to SORT1, or (b) any Patent to the extent Covering the binding portion(s) of an Antibody or other compound that is not directed to SORT1, in each case (a) and (b), unless such Antibody or compound was clinically Developed or Commercialized by the applicable licensor Party in the performance of activities under this Agreement. For purposes of the foregoing, "directed to SORT1" means [\*\*\*].

3.10 Joint Patents.

[\*\*\*]

# ARTICLE IV DEVELOPMENT

4.1 General.

41

**4.1.1** <u>JDC Oversight</u>. The JDC shall coordinate the Development of Cost Profit Sharing Products, provide a forum for communicating with respect to Development of other Licensed Products in the Territory, and perform such other functions with respect to Development of Licensed Products as are provided for herein. The JDC will, subject to the JSC's oversight, direct the clinical and regulatory program for the Cost Profit Sharing Products.

**4.2** <u>GDP</u>; <u>Non-Core GDP</u>; <u>Amendments</u>; <u>Development Responsibilities</u>.

# **4.2.1** Global Development Plan and Non-Core Global Development Plan.

(a) <u>Core Development Activities</u>. The conduct of all GLP toxicology studies or other IND enabling studies, and Clinical Studies in support of the Core Dossier, of Cost Profit Sharing Products shall be governed by the GDP, and the Parties agree to conduct all such activities in accordance with the GDP. The Initial GDP is attached hereto as <u>Exhibit 1.58</u> (which also includes overall total budget figures for the initial Development Budget as described in Section 4.2.3, and budget forecasts for subsequent periods as described in Section 4.2.5(b)). The GDP shall allocate responsibility for each Development activity set forth in the GDP to a Party. The GDP shall include general study design parameters, specific staffing requirements and the funding budget for each stage of clinical development for each Indication in the GDP, and shall be consistent with the terms of this Agreement. Guidelines for additional data and/or criteria, if any, to be generated for assessment prior to commencement of any specific Clinical Study shall be included in the GDP. The terms of and activities set forth in the GDP shall at all times be designed to be in compliance with all applicable Laws and Good Clinical Practice and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account, in accordance with Section 4.3.7, the Relevant Internal Policies.

(b) Non-Core Development Activities. The conduct of all GLP toxicology studies or other IND enabling studies and Clinical Studies that are (i) for any Cost Profit Sharing Products that are not in support of the Core Dossier or (ii) otherwise for Opt Out Products shall be governed by and set forth in the Non-Core GDP, and GSK agrees to conduct all such activities at its sole expense in accordance with the Non-Core GDP. The Non-Core GDP shall be developed by GSK, submitted to the JDC for review and discussion prior to commencement of such activities and shall be consistent with the terms of this Agreement and the Global Regulatory Strategy. The terms of and activities set forth in the Non-Core GDP shall at all times be designed to be in compliance with all applicable Laws and to be conducted in accordance with professional and ethical standards customary in the pharmaceutical industry, taking into account where required by Law, GSK's health care compliance policies and applicable SOPs. Alector's representatives on the JDC shall be kept reasonably informed with regard to the development of such Non-Core GDP by GSK, provided that such consultation shall not delay GSK from developing such Non-Core GDP in accordance with its internal schedule for such development. The Non-Core GDP shall be in such format reasonably developed by GSK in accordance with its ordinary business practices for such activities, provided that in no event shall GSK be required to provide copies of its internal governance documents.

42

- **4.2.2** <u>Development Principles</u>. It is the intent of the Parties that Development of Licensed Products in the Field will be conducted in accordance with the following principles except to the extent (if any) otherwise expressly provided in the thencurrent GDP established in accordance with Section 4.2.1 or 4.2.5 (as applicable), and the JDC (or the JSC, or the Executive Officers, as applicable) shall take into account and attempt to implement the following principles in its decision-making, including preparation, review and approval of any updates to and amendments of the GDP:
- (a) Regardless of the specific division of responsibility between the Parties for particular activities at any particular time, the JDC shall serve as a conduit for sharing information, knowledge and expertise relating the Development of the Licensed Antibodies and Licensed Products.
- (b) Clinical development of Cost Profit Sharing Products should be performed according to a single, integrated global program.
- (c) Except with respect to Opt Out Products following Alector Opt Out, the GDP should at all times include a meaningful role for both Parties. In allocating responsibilities between the Parties, the JDC (or the JSC, or the Executive Officers, if applicable) shall take into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities.
  - (d) After receipt of a Regulatory Approval of a Licensed Product for an Indication [\*\*\*].
- **4.2.3** <u>Development Budget</u>. The Development Budget included in the GDP shall be a rolling budget setting forth the budgeted amounts for Development Costs with respect to activities allocated to the Parties in support of the Core Dossier under the GDP. The Development Budget shall include for each Party a budget for Development Costs for the Development activities allocated to such Party: (a) during a given Calendar Year ([\*\*\*]); (b) a good faith forecasted budget, in reasonable detail, for the [\*\*\*] Calendar Years (broken down by Calendar Year), and (c) [\*\*\*]. The Development Budget shall also include a breakout of costs by FTE and Out-of-Pocket Costs as determined by the Finance Working Group. The budget amounts indicated in the Initial GDP will constitute the initial Development Budget. Promptly after the Effective Date the Finance Working Group, in consultation with project management from each Party, will allocate the amounts in initial Development Budget to each Party based on the activities that each Party conducts under the GDP. Concurrently with the annual update of the GDP in accordance with Section 4.2.5, the JDC shall also prepare, and the JSC shall review and approve, an annual Development Budget covering the next Calendar Year and forecasted estimates through receipt of Regulatory Approval in [\*\*\*] for each Indication then included in the GDP.

#### **4.2.4** Allocation of Development Activities.

43

- (a) The GDP shall allocate responsibility between the Parties for the conduct of Clinical Studies and the various other Development activities addressed in the GDP. Unless otherwise approved by the JDC, with respect to Development of Licensed Products in the Field, (a) Alector shall be responsible for (i) all GLP toxicology studies and other studies intended to support an IND filing, (ii) Phase I Clinical Studies, (iii) all Development activities for Minor Indications and (iv) all Development activities for Major Indication other than any Phase III Clinical Study for a Major Indication or Post-Approval Required Study for a Major Indication, in each case (ii) (iv), for Cost Profit Sharing Products in support of the Core Dossier, and (b) GSK shall be responsible for (X) any Phase III Clinical Study or Post-Approval Required Study for Major Indications for Cost Profit Sharing Products in support of the Core Dossier, (Y) all Development activities necessary to obtain Regulatory Approval for Major Indications and Minor Indications in the OUS Territory for Cost Profit Sharing Products that are not in support of the Core Dossier (i.e., Development activities that are specific to a country outside of [\*\*\*]), and (Z) all Development activities for Opt Out Products.
- (b) Neither Party nor its Affiliates shall conduct any GLP toxicology studies or other IND enabling studies intended to support an IND filing for any Licensed Product, or any Clinical Study for any Licensed Product, in each case other than a Cost Profit Sharing Product under the GDP or Non-Core GDP or an Opt-Out Product. Any such GLP toxicology study or other IND enabling study intended to support an IND filing or Clinical Study of a Licensed Antibody or Licensed Product shall be subject to the governance and oversight by both Parties as set forth in ARTICLE II and this ARTICLE IV.

#### **4.2.5** <u>Updating and Amending the GDP</u>.

(a) The JDC shall review the GDP not less frequently than annually and shall develop detailed and specific GDP updates, which shall include the Development Budget for the subsequent Calendar Year and forecasted estimates for the succeeding Calendar Years for at least the period thereafter until Regulatory Approval of Cost Profit Sharing Products for each Indication in the GDP in [\*\*\*]. The JDC shall submit all such updates to the JSC for review and approval, such that JSC preliminary approval would occur no later than [\*\*\*] of each Calendar Year. Upon the JSC's preliminary approval, such updates shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [\*\*\*] of each Calendar Year, at which time any updates shall be appended to the GDP. The JDC may also develop and submit to the JSC from time to time other proposed substantive amendments to the GDP. The JDC shall also review each Party's (and its Affiliates') performance under the then-current GDP (including the Development Budget) on a [\*\*\*] basis, and shall develop detailed and specific updates and substantive amendments to the Development Budget that reflect such performance. The JSC shall review proposed amendments presented by the JDC and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon such approval by the JSC, the GDP shall be amended accordingly. Amendments and updates to the GDP, including the Development Budget, shall not

44

be effective without the approval of the JSC (or a decision or determination pursuant to Section 13.1 or Section 13.3, if applicable). In the event that the JSC does not approve an updated GDP, including the Development Budget, prior to the start of the next Calendar Year, either Party may initiate procedures to resolve the issue pursuant to Sections 13.1 and 13.3, and the thencurrent GDP, and the forecasted amounts set forth for the applicable Calendar Year of the Development Budget shall continue to apply until the GDP is agreed by the JSC or decided or determined pursuant to Section 13.1 or Section 13.3.

(b) The Initial GDP includes a high-level forecast of anticipated budget amounts and associated timelines for Development of Licensed Products. In reviewing and approving annual updates or amendments to the Development Budget, the JSC (or the Executive Officers pursuant to Section 13.1 or the Parties, if applicable) shall consider the budget amounts and timelines reflected in the Initial GDP. The Development Budget shall provide for at least the amounts reflected for the relevant year in Initial GDP (or, if different, the amounts forecast for the relevant year in the Last Agreed Budget, taking into account any amounts actually spent for the years covered by such Development Budget that have already occurred), on approximately the timelines reflected in the Initial GDP, unless the Parties otherwise agree that spending such amounts on such timelines is not commercially reasonable for Development of a Cost Profit Sharing Product (viewing the Cost Profit Sharing Product on a standalone basis and not taking into account, for example, either Party's own portfolio management considerations).

# **4.2.6** <u>Independent Development Activities</u>. [\*\*\*]

(a) *Independent Performance of Activities*. Alector may, upon notice to GSK, initiate and conduct the Development activities in such [\*\*\*] (each, an "**Independent ADA**"); provided, however, that if GSK determines reasonably and in good faith that any of the proposed Development activities are reasonably likely to adversely affect the Development or Commercialization of the applicable Licensed Product in the Field, then Alector shall not undertake such Independent ADA unless and until the JDC or JSC determines that such Independent ADA should be permitted. For clarity, a Licensed Product that is the subject of an Independent ADA shall continue to be a "Licensed Product" for all purposes of this Agreement (except as otherwise set forth in this Section 4.2.6). Alector shall provide informal reports of its progress with regard to the Independent ADAs at each meeting of the JDC and shall provide formal written reports of the results and budgeted costs of the Independent ADAs to the JDC at least [\*\*\*] during the first [\*\*\*] [\*\*\*] in which any Clinical Study within an Independent ADA is being performed, and otherwise in the same manner and frequency as the Parties provide reports to the JDC with respect to activities covered by the GDP. If [\*\*\*] (such use "**ADA Data Use**" and [\*\*\*], the "**ADA Data Use Date**"), then such Party shall promptly, in any event within [\*\*\*] [\*\*\*], notify the other Party.

(b) *Costs of Independent Development Activities*. Subject to Section 4.2.6 below, Alector shall bear all costs associated with the Independent ADA it undertakes and such costs shall not be taken into account as Development Costs for purposes of Section 4.5, and costs

45

associated with the Independent ADA shall not be taken into account as Development Costs for purposes of determining Excess Costs pursuant to Section 4.5.4. If ADA Data Use occurs, then GSK shall reimburse Alector an amount equal to the applicable ADA Cost Percentage of the costs incurred prior to the ADA Data Use Date by Alector and its Affiliates for such Independent ADA. Such costs will be determined using the same manner of calculating Development Costs under the GDP. As used herein, the "ADA Cost Percentage" means (X) with respect to the first Independent ADA, [\*\*\*] for Development Costs other than Manufacturing Costs which would have been shared equally and [\*\*\*] for Manufacturing Costs which would have been shared equally and [\*\*\*] for Development Costs other than Manufacturing Costs which would have been shared equally.

- (c) *ADA Phase III Milestones*. Notwithstanding Section 7.2.1, if Alector undertakes Independent ADAs, GSK shall not be obligated to make any payments for Clinical Study Milestones pursuant to Sections 7.2.1 on the basis of Clinical Study Milestones achieved in connection with such Independent ADAs ("**ADA Phase III Milestones**") [\*\*\*] and such Clinical Study Milestones shall not be considered achieved with respect to such Independent ADAs until fully paid as set forth in this Section 4.2.6(c).
- (i) *First Independent ADA*. For the achievement of any ADA Phase III Milestone in connection with the first Independent ADA the milestone payment amount under Sections 7.2.1 owed for the achievement of such ADA Phase III Milestone in connection with such Independent ADA shall become due and payable to Alector upon the ADA Data Use Date for such Independent ADA.
- (ii) *Second and Later Independent ADA*. For the achievement of any ADA Phase III Milestone in connection with the second or later Independent ADA, [\*\*\*] ([\*\*\*]) [\*\*\*].

(iii) [\*\*\*]

(d) *ADA Approval Milestones*. Notwithstanding Section 7.2.2 and Section 7.2.3, for any Regulatory Approval achieved using Data generated from Independent ADAs in a substantive manner as the basis therefor or achievement of any First Commercial Sale on the basis of any such Regulatory Approval ("ADA Approval Milestone"), an amount equal to the ADA Approval Percentage of the corresponding amount for achievement of the Approval Milestone under Sections 7.2.2 or the Commercial Milestone under Section 7.2.3, as the case may be, shall become due and payable to Alector upon achievement of such Approval Milestone or Commercial Milestone, as the case may be. As used herein, the "ADA Approval Percentage" means (A) [\*\*\*] with respect to an ADA Approval Milestone for each subsequent Independent ADA.

46

**4.2.7** <u>Development of Licensed Products for Minor Indications and Major Indications</u>. Notwithstanding anything in this Agreement to the contrary (including Section 4.2.6), unless the Parties otherwise mutually agree, or there has been an Alector Opt Out for all Licensed Antibodies, neither Party (nor its Affiliates or Sublicensees) shall [\*\*\*].

# 4.3 Development Efforts; Manner of Performance; Reports.

**4.3.1** <u>Development Efforts.</u> The Parties shall use Commercially Reasonable Efforts to Develop and to seek and obtain Regulatory Approval for [\*\*\*]. Each Party and its Affiliates shall conduct its Development activities in good scientific manner and in compliance with applicable Law, including laws regarding environmental, safety and industrial hygiene, and Good Laboratory Practice, Good Clinical Practice, Informed Consent and Institutional Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Notwithstanding anything to the contrary contained herein, a Party or its Affiliates shall not be obligated to undertake or continue any Development activities with respect to the Licensed Antibodies or Licensed Products if such Party (or Affiliates) reasonably determines that performance of such Development activity would violate applicable Law or such Party determines (which determination in the case of GSK is made by the GSK Global Safety Board) with respect to a conduct of a Clinical Study, that such Clinical Study would pose an unacceptable safety risk for subjects participating in such Clinical Study (taking into account the potential benefits).

# **4.3.2** Right to Subcontract Development Activities.

(a) Required Subcontract Terms. Each Party or its Affiliate may subcontract the performance of any Development activities undertaken in accordance with this Agreement to one or more Subcontractors pursuant to Subcontract which shall be consistent with the terms and conditions of this Agreement, shall contain confidentiality provisions no less restrictive than those set forth in ARTICLE IX, and shall contain a certification that such Third Party subcontractor has not been debarred, and is not subject to debarment, pursuant to Section 306 of the United States Federal Food, Drug and Cosmetics Act, and is not the subject of a conviction described in such section. The JDC shall oversee the performance of Subcontractors under Material Subcontracts in the same manner and to the same extent as its oversight of the Parties hereunder. Notwithstanding the foregoing, the subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Subcontractors with the applicable provisions of this Agreement.

(b) *Obligation to Discuss*. Notwithstanding the foregoing, if either Party (or its Affiliate) desires to subcontract any of its assigned Development activities, such Party shall first discuss it with the other Party and take into account and reasonably consider amending the GDP to reallocate such activities to the other Party or alternatively, subcontracting such activities to the other Party (at a cost to be agreed between the Parties), taking into account (balanced with

47

other factors) the capabilities of the other Party and potential impact on costs, as a potential alternative to subcontracting such activities to a Third Party. In the event that any Development activity allocated to one Party under the GDP is subcontracted to the other Party (as opposed to being allocated to the other Party under the GDP), then if the subcontracting remains ultimately responsible under this Agreement for the conduct of such activities, the other Party shall conduct such activities under the management of, and as directed by, the subcontracting Party, consistent with the terms of this Agreement and all applicable Laws.

- (c) [\*\*\*] *Material Subcontracts*. If, following the discussion required under Section 4.3.2(b), a Party (or its Affiliate) still desires to subcontract the performance of a Development activity hereunder to one or more Third Parties, it may proceed to do so, subject to compliance with this Section 4.3.2(c). Prior to entering into any Material Subcontract, [\*\*\*].
- (d) *Manufacturing Activities*. Notwithstanding the foregoing, any subcontracting of Manufacturing activities in connection with Development shall be subject to Section 6.1.3.
- (e)\_Coordination with Co-Exclusive Rights. It is understood that the co-exclusive licenses granted by Alector to GSK under Section 3.1 above shall not be construed to limit Alector's and its Affiliates' right to engage Subcontractors in accordance with this Section 4.3.2 (or under Section 5.2.1, or to engage Manufacturing Subcontractors in accordance with Section 6.1.3).
- **4.3.3** <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Development activities for which it (or its Affiliate) has or otherwise is assigned responsibility under this Agreement or the GDP and shall keep the other Party reasonably informed as to the progress of such activities.
- **4.3.4** <u>Development Reports</u>. At each meeting of the JDC, each Party will report on the Development activities such Party and its Affiliates has performed or caused to be performed since the last meeting of the JDC as allocated to such Party under the GDP, evaluate the work performed in relation to the goals of the GDP and provide such other information as may be reasonably requested by the JDC with respect to such Development activities. If a Party fails to adequately provide such report at a meeting of the JDC, the other Party may request, and such Party will provide to such other Party, a written progress report that includes information regarding accrual, site initiation, progress on protocol writing, meeting requests and briefing documents, in the case of clinical or regulatory activities, and in other cases such information as is reasonably necessary to convey a reasonably comprehensive understanding of the status of the applicable Development activity.
- **4.3.5** <u>Compliance Audits</u>. With respect to any facility or site at which a Party, its Affiliates or its Subcontractor conducts Development activities pursuant to this Agreement or the GDP, the other Party shall have the right, at its expense, upon [\*\*\*] [\*\*\*] written notice to the

48

such Party (and if applicable, such Affiliate or as described below, Subcontractor), and during normal business hours, to inspect such site and facility and any records relating thereto [\*\*\*] [\*\*\*], or more often with cause, to verify the other Party's compliance with the terms of this Agreement relating to all applicable Laws, including Good Laboratory Practices, Good Clinical Practices and current standards for pharmacovigilance practice. Such inspection shall be subject to the confidentiality provisions set forth in ARTICLE IX and rights to conduct such inspection as set forth in the applicable Subcontract. Each Party shall use Commercially Reasonably Efforts to include in any contract or other written arrangement with its Subcontractors, a clause permitting the other Party to exercise its rights under this Section 4.3.5.

- **4.3.6** <u>Quality Assurance Audits</u>. GSK will be responsible for establishing audit plans for each Clinical Study assigned to GSK in the GDP according to GSK's internal SOP. Alector's quality assurance department will be responsible for establishing audit plans for each Clinical Study assigned to Alector in the GDP according to Alector's internal SOP. The JDC shall form a joint Oversight/Quality Working Group (the "**Oversight/Quality Working Group**") and such Oversight/Quality Working Group may review and provide comments on the audit plans established by GSK and Alector's quality assurance personnel. GSK and Alector's quality assurance personnel will each consider in good faith all such comments submitted by the Oversight/Quality Working Group, but GSK and Alector's quality assurance personnel shall each have final decision-making authority with respect to the audit plans it develops.
- **4.3.7** <u>Development Standards</u>, <u>Relevant Internal Policies</u>. Each Party will perform, and ensure that their Affiliates, Sublicensees, and subcontractors perform, its Development activities as contemplated under this Agreement in a good scientific manner and in compliance with its Relevant Internal Policies, applicable Law, including (if applicable) laws regarding the environment, safety and industrial hygiene, and GMP, GLP, GCP, informed consent, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Each Party and its Affiliates will maintain written or electronic records of the Development activities conducted under the GDP, including without limitation data and results resulting therefrom, in sufficient detail, in a good scientific manner (in accordance with GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that (a) are complete and accurate in all material respects and properly reflect all Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates under this Agreement and (b) record the technical and scientific details for such Development work performed and results achieved, and the source records and primary data for such results shall not include or be commingled with records of activities outside the scope of this Agreement, which records will be retained for at least [\*\*\*] ([\*\*\*]) [\*\*\*] following expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law or such Party's Relevant Internal Policies. [\*\*\*].
  - 4.4 Regulatory Submissions and Regulatory Approvals.

49

- **4.4.1** Regulatory Responsibilities. The Party conducting the applicable Clinical Study under the GDP shall be responsible for Regulatory Filings and interactions with the applicable Regulatory Authorities with respect to such Clinical Study.
- **4.4.2** Ownership of Regulatory Filings and Regulatory Approvals. Subject to Section 4.4.1, all Regulatory Filings submitted to a Regulatory Authority, including all applications, for Regulatory Approvals for the Cost Profit Sharing Products in the Field in the United States shall be in the name of and owned by Alector for Licensed Products containing AL001 (other than with respect to an Opt Out Product) and in the name of GSK for Licensed Products containing AL101 (or any Opt Out Product). Subject to Section 4.4.1, all Regulatory Filings submitted to a Regulatory Authority, including all applications, for Regulatory Approvals for the Cost Profit Sharing Products in the Field in the OUS Territory and otherwise for Opt Out Products in the Field shall be in the name of and owned by GSK. To the extent a Party or its Affiliate is performing Development activities, in each case in accordance with this Agreement, the other Party shall cooperate fully, including by making such Regulatory Filings and submissions available, and undertaking such regulatory interactions as the Party performing (or whose Affiliate is performing) such Development activities may reasonably request for such purposes. Upon (a) the determination by GSK to Initiate a Phase III Clinical Study of a Cost Profit Sharing Product for a Major Indication, (b) the date a Licensed Product becomes an Opt Out Product or (c) the date which a Party (or its successor-in-interest) is required to permanently cease Commercialization activities with respect to a Licensed Product pursuant to this Agreement (including Section 5.1.3(d)), the Parties, through the Clinical/Regulatory Working Group, shall cooperate to transfer the appropriate Regulatory Filings for such Licensed Product as soon as reasonably practicable or at a time determined by the Clinical/Regulatory Working Group.
- 4.4.3 Regulatory Cooperation. Subject to applicable Law, each Party shall have the right [\*\*\*] pertaining to Development of the Cost Profit Sharing Products in the Field or Regulatory Approval of a Cost Profit Sharing Products [\*\*\*]. Each Party shall, to the extent possible, provide the other Party with reasonable advance notice of all such meetings and other contact and advance copies of all related documents and other relevant information relating to such meetings or other contact. Each Party shall provide the Clinical/Regulatory Working Group with advance drafts of any material documents or other material correspondence pertaining to Regulatory Approvals, including any proposed labeling, that such Party plans to submit to any Regulatory Authority and keep the Clinical/Regulatory Working Group informed of all material regulatory interactions with Regulatory Authorities that pertain to the Cost Profit Sharing Products in each case in [\*\*\*]. The Clinical/Regulatory Working Group may provide comments regarding such documents and other correspondence prior to their submission, which comments the submitting Party shall consider in good faith. Each Party shall provide the other Party (through the Clinical/Regulatory Working Group) with copies of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to a Regulatory Approval that pertains to the Cost Profit Sharing Products. Notices, copies of submissions and correspondence, and other materials to be given in advance as provided in this Section 4.4.3 shall be provided at least [\*\*\*]

50

[\*\*\*] in advance unless circumstances necessitate a shorter time period, and in any event not less than a reasonable time in advance under the circumstances.

**4.4.4** Rights of Reference and Access to Data. Each Party shall have the right to cross-reference the other Party's or its Affiliate's drug master file ("DMF") and/or IND, if any, and any other Regulatory Filings anywhere in the world related to Cost Profit Sharing Products (and, for clarity, GSK shall also have the right to cross-reference such filings with respect to any Opt Out Products it is Developing and/or Commercializing), [\*\*\*]. Each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent exclusive right of access/reference in the United States or in any other country or region of the OUS Territory, to any Data, including such Party's or its Affiliate's clinical dossiers, Controlled by such Party or such Affiliate that relates to a Cost Profit Sharing Products for use by the other Party to Develop and Commercialize the Cost Profit Sharing Products (and with respect to GSK, any Licensed Product) in the Field pursuant to this Agreement. Each Party or such Affiliate shall provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in the United States or any country or region of the OUS Territory or otherwise provide appropriate notification of such right of the other Party to the applicable Regulatory Authority.

**4.4.5** Regulatory Audits. The Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Studies or Manufacturing of Cost Profit Sharing Products in the Field are conducted by or on behalf a Party pursuant to this Agreement, whether such site or facility is such Party's or its Affiliate's or Subcontractor's (each an "Audited Site"). Each Party shall be given a reasonable opportunity, at its own cost, (taking into account the timing and notice provided by the applicable Regulatory Authority) to assist in the preparation of the other Party's Audited Sites for inspection, where appropriate, and to attend any inspection by any Regulatory Authority of the other Party's Audited Sites, and the summary, or wrap-up, meeting with a Regulatory Authority at the conclusion of such inspection. If such attendance would result in the disclosure to the other Party of Confidential Information unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering such unrelated subject matter. In the event that any Audited Site is found to be noncompliant with one or more Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice or current standards for pharmacovigilance practice, the non-compliant Party shall submit to the other Party a proposed recovery plan or Corrective and Preventative Actions ("CAPA") within [\*\*\*] [\*\*\*] after such non-compliant Party, its Affiliate or its Subcontractor receives notification of such non-compliance from the relevant Regulatory Authority and such non-compliant Party shall use Commercially Reasonable Efforts to implement such recovery plan or CAPA promptly after submission. Notwithstanding the foregoing, the rights of each Party under this Section 4.4.5 are subject to the terms of the applicable Subcontract, provided that each Party agrees to use Commercially Reasonable Efforts to include in the applicable Subcontract with its Subcontractors, a clause permitting the other Party to exercise its rights under this Section 4.4.5.

51

**4.4.6** Pricing and Reimbursement Approvals. Subject to Section 5.7, GSK or its Affiliate shall be responsible for and have the exclusive right to seek and attempt to obtain pricing and reimbursement approvals for the Cost Profit Sharing Products in the Field in the U.S. and in the OUS Territory and otherwise for Opt Out Products in the Field, provided that GSK shall keep Alector reasonably informed with regard to the price of the Cost Profit Sharing Products in [\*\*\*] and shall discuss with, and consider in good faith the comments of, the JCC with respect to the price of Cost Profit Sharing Products in the U.S.

# **4.5** Costs of Joint Development.

#### 4.5.1 Cost Sharing.

- (a) Subject to Section 4.5.5, Development Costs incurred during the Term by the Parties for Cost Profit Sharing Products shall be borne as follows:
- (i) Development Costs (other than Manufacturing Costs) for the conduct of the first Phase II Clinical Study for each of [\*\*\*] specified in the Initial GDP: 100% by Alector and 0% by GSK;
  - (ii) Manufacturing Costs: 50% by GSK and 50% by Alector; and

(iii) all other Development Costs (other than Manufacturing Costs) not included within the foregoing clause (i) and (ii) (including for clarity all Development Costs (other than Manufacturing Costs) incurred in support of the Core Dossier): 60% by GSK and 40% by Alector.

For the avoidance of double-counting, the Parties acknowledge and agree that Development Costs shall not be included in Allowable Expenses for purposes of calculating Pre-Tax Profit or Loss in accordance with the Financial Exhibit (and, likewise, that any amounts included in Allowable Expenses shall not be included in Development Costs). Payments under Existing Third Party Agreements incurred after the Effective Date that are attributable and allocable to the Development activities for which the Parties share (or reimburse) Development Costs under this Agreement shall be included as Development Costs shared (or reimbursed, as applicable) by the Parties.

**4.5.2** Clinical Studies Involving Other Products of a Party. Notwithstanding Section 4.5.1 above, in the case of Clinical Studies and other Development activities under the GDP involving another product of a Party (including any product of its Affiliate) (*i.e.*, other than a "Cost Profit Sharing Product") as a comparator or combination therapy, then the Party whose other product is involved shall supply such other product for purposes of such trial or activity at the manufacturing cost thereof (calculated in the same manner as Supply Cost for a Cost Profit Sharing Product) and the portion of the costs of such Clinical Study to be including in Development Costs of such Clinical Study shall be reasonably determined by the Finance Working Group, based on

52

the relative benefit to the Licensed Product and the other product(s) of a Party involved in such Clinical Study.

**4.5.3** Development Costs Reports. Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 4.5.4. Each Party shall calculate and maintain records of Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the Finance Working Group, and quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs will be determined by the Finance Working Group (the "Development Reconciliation Procedures"). Such procedures will provide the ability to comply with financial reporting requirements of each Party. The Development Reconciliation Procedures shall provide that a preliminary estimate of the Development Cost, in a format established by the Finance Working Group, shall be provided by each of Alector and GSK by the [\*\*\*] [\*\*\*] of the [\*\*\*] [\*\*\*] of each Calendar Quarter for purposes of financial statement close process. Within [\*\*\*] [\*\*\*] after the end of each Calendar Quarter, each Party shall submit to the Finance Working Group and the JDC a report, in such reasonable detail and format as is established by the Finance Working Group, which format shall be consistent with the categories calculated by the reporting Party in accordance with its Accounting Standards and sufficiently detailed to permit the other Party to obtain a reasonable understanding of, of all Development Costs incurred by such Party during such Calendar Quarter. Within [\*\*\*] [\*\*\*] following the receipt of such report, each Party shall have the right to request reasonable additional information related to the other Party's and its Affiliates' Development Costs during such Calendar Quarter in order to confirm that such other Party's spending is in conformance with the approved Development Budget and to finalize a written report, as described in Section 4.5.4(g). The Finance Working Group shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes.

#### **4.5.4** Excess Costs; Reimbursement of Development Costs.

- (a) <u>Notification of Excess Costs</u>. Each Party shall notify the other Party without undue delay upon becoming aware that the anticipated Development Costs to be incurred by such Party for a Cost Profit Sharing Product for a given Calendar Quarter or Calendar Year might be in excess of the Last Agreed Budget for such Cost Profit Sharing Product for such Calendar Quarter or Calendar Year period. Following such notification, the Finance Working Group shall discuss the causes of any such increase and evaluate potential mitigation measures to prevent a further increase of Development Costs as applicable.
- (b) <u>Permitted Overage</u>. To the extent the FTE Costs and Out-of-Pocket Costs within Development Costs incurred by or on behalf of a Party in a Calendar Year do not exceed [\*\*\*] of the aggregate annual amounts budgeted for such FTE Costs and Out-of-Pocket Development Costs, respectively, to be incurred by or on behalf of the concerned Party for all of its activities for Cost Profit Sharing Products in such Calendar Year as set forth in the Last Agreed

53

Budget (the "**Permitted Overage**"), such costs or expenses within the Permitted Overage shall be included in the calculation of the applicable Development Costs for the purposes of calculating the Development Cost sharing pursuant to Section 4.5.1. Notwithstanding the foregoing, to the extent that [\*\*\*]. However, if [\*\*\*].

- (c) JSC Discussion. If the Finance Working Group concludes that:
- (i) the anticipated amount of the applicable Development Costs is likely to exceed the Permitted Overage (such amount the "Anticipated Excess Costs"); and
- (ii) there are no mitigation measures to prevent such Anticipated Excess Costs that the Parties agree to implement, the JSC shall discuss in good faith a corresponding amendment of the concerned Development Budget to reflect the Anticipated Excess Costs.
- (d) <u>Responsibility for Excess Costs</u>. In the event that the Development Costs incurred by or on behalf of a Party in a Calendar Year exceed the Permitted Overage for such Calendar Year (such excess Development Costs incurred, the "Excess Costs"), then, except as set forth Section 4.5.4(e) and 4.5.4(f), the applicable Party incurring such Excess Costs shall be solely responsible for bearing such Excess Costs in excess of the applicable Permitted Overage and such Excess Costs shall not be included in the calculation of the applicable Development Costs for purposes of calculating the Development Cost sharing pursuant to Section 4.5.1.
- (e) Carry Forward. If any Excess Costs are excluded from sharing by the Parties for a particular Calendar Year pursuant to the foregoing in Section 4.5.4(d), such Excess Costs shall be carried forward to subsequent Calendar Years and, to the extent the total Development Costs, as applicable, incurred by such Party and its Affiliates for the subsequent Calendar Year are less than [\*\*\*] of the aggregate Development Costs allocated to such Party under the Last Agreed Budget for such Calendar Year, such carried forward amounts shall be included in Development Costs, as applicable, to be shared by the Parties for such Calendar Year period (i.e., so that the total Development Costs incurred by such Party and its Affiliates that are shared pursuant to this paragraph do not exceed [\*\*\*] of the Development Costs allocated to such Party under the Last Agreed Budget for the applicable Calendar Year). Additionally, to the extent the Development Costs for a given Calendar Year are less than the Development Costs included in the Development Budget for such Calendar Year, because Development activities planned for such Calendar Year have been delayed to a subsequent Calendar Year, the Finance Working Group shall adjust the Development Budget for subsequent Calendar Years to reflect such delay (but without increasing the total cumulative Development Costs under the Development Budget).
- (f) Excess Costs Automatically Included as Development Cost. Notwithstanding the foregoing, to the extent that Excess Costs incurred by a Party are directly attributable to [\*\*\*], then such Excess Costs shall not be borne solely by the Party incurring such

54

Excess Costs and shall be included in the calculation of the applicable Development Costs for purposes of calculating the Development Cost sharing pursuant to Section 4.5.1.

(g) Reimbursement of Development Costs. The Development Reconciliation Procedures shall provide for the Finance Working Group to develop a written report setting forth in reasonable detail the calculation of any net amount owed by Alector to GSK or by GSK to Alector, as the case may be, as necessary to accomplish the sharing of Development Costs set forth in Section 4.5.1 and this Section 4.5.4, and to prepare such report promptly following delivery of the report described in Section 4.5.3 and in a reasonable time (defined in Section 7.6.5) in advance of payment. The Party that is due reimbursement of Development Costs shall invoice the other Party within [\*\*\*] ([\*\*\*]) [\*\*\*] of receipt of the finalized report described in Section 7.6.5 from the Finance Working Group. Such payments by one Party to reimburse the other Party's expenditures for Development Costs shall be payable [\*\*\*] ([\*\*\*]) [\*\*\*] following receipt of the foregoing invoice. In establishing the Development Reconciliation Procedures, the Finance Working Group shall work to coordinate and harmonize all Reconciliation Procedures to permit for reconciliation, and associated payments, with respect to Development Costs as well as Pre-Tax Profit or Loss in the United States and royalties in the OUS Territory and on Opt Out Products in the United States.

# 4.5.5 Alector Opt Out.

- (a) <u>Exercise</u>. On a Licensed Antibody-by-Licensed Antibody basis, Alector may, upon [\*\*\*] [\*\*\*] advance written notice to GSK, opt out of sharing Development Costs and Pre-Tax Profits or Loss for such Licensed Antibody and all Cost Profit Sharing Products containing such Licensed Antibody for all Indications (each such opt out with respect to a Licensed Antibody, an "Alector Opt Out", the date such notice is provided, the "Opt Out Notice Date" and the date of expiration of such [\*\*\*] [\*\*\*] period with respect to such Alector Opt Out, the "Alector Opt Out Date"), provided that Alector may not exercise the Alector Opt Out with respect to a Licensed Antibody during the Launch Window for a Cost Profit Sharing Product containing such Licensed Antibody. As used herein, "Opt Out Product" means any Licensed Product containing a Licensed Antibody for which the Alector Opt Out has been exercised.
- (b) <u>Consequence of Alector Opt Out</u>. Following the Alector Opt Out Date with respect to an Opt Out Product:
- (i) For any Clinical Studies for which Alector solely bears the cost under Section 4.5.1(a)(i) and still remain to be conducted under the then-current GDP, Alector shall [\*\*\*];
- (ii)\_Alector shall not be obligated to share in costs incurred after the Alector Opt Out Date with respect to the Development of Licensed Products for the Opt Out Product, or with respect to any Clinical Study directed to the Opt Out Product that is [\*\*\*];

55

(iii) Except for Clinical Studies for the Opt Out Product where Alector remains responsible for Development Costs pursuant to the preceding Sections 4.5.5(b)(i) and 4.5.5(b)(ii) (the "Committed Opt Out Cost Share Studies"), GSK shall reimburse Alector for all costs incurred by Alector in the Development of the Opt Out Products, including for Manufacturing activities in support thereof and the Supply Cost for any Opt Out Product provided by Alector to GSK;

(<u>iv</u>)\_Alector shall not be entitled to receive, nor obligated to pay, a share of any Pre-Tax Profit or Loss with respect to such Opt Out Product pursuant to Section 7.3 and shall, instead receive royalties on Net Sales of such Opt Out Product pursuant to Section 7.4.2;

- (v) Except where such Alector Opt Out is [\*\*\*];
- (vi) except with respect to the Committed Opt Out Cost Share Studies: [\*\*\*];
- (vii) GSK shall [\*\*\*];

(viii) the licenses granted in Section 3.1 with respect to Licensed Products shall become exclusive with respect to the Opt Out Products (except as set forth in Sections 4.5.5(b)(i) or 4.5.5(b)(ii)); and

(ix) the licenses granted in Section 3.2 with respect to such Licensed Products shall terminate with respect to the Opt Out Products (except as set forth in Sections 4.5.5(b)(i) or 4.5.5(b)(ii)).

#### **4.6** New Product Decisions.

#### **4.6.1** Definitions. As used herein:

- (a) "Alector Independent Know-How" means Know-How that [\*\*\*].
- (b) "Alector Independent Patents" means Patents that [\*\*\*].
- (c) "**Alector Independent Technology**" means Alector Independent Know-How and Alector Independent Patents.
  - (d) "GSK Independent Know-How" means Know-How that [\*\*\*].
  - (e) "GSK Independent Patents" means Patents that [\*\*\*].
  - (f) "GSK Independent Technology" means GSK Independent Know-How or GSK Independent Patents.

56

- (g) "**Independent Technology**" means the Alector Independent Technology or the GSK Independent Technology.
- (h) "New Product Decision" means a decision by the JDC with respect to the following matters: (i) a GDP providing for the conduct of Clinical Studies, GLP toxicology studies or other studies intended to support an IND filing, with respect to any Licensed Antibody other than an Existing Antibody, or any Licensed Product other than an Existing Product, including a Licensed Product consisting of a different formulation of an Existing Product, (ii) perform Manufacturing activities in support of the activities described in the foregoing clause (i), or (iii) the Commercialization (or Manufacture for Commercialization) of any Licensed Antibody other than an Existing Antibody, or any Licensed Product other than an Existing Product.

# 4.6.2 Advancement of Licensed Antibody or Licensed Product other than an Existing Antibody or Existing Product.

- (a) Neither Party shall [\*\*\*], unless such Party proposes a New Product Decision with respect to such Licensed Antibody or Licensed Product to the JDC for approval and the Parties unanimously approve such New Product Decision (themselves or their representatives on the JDC or their Executive Officers pursuant to Section 13.1).
- (b) Each Party will have [\*\*\*] [\*\*\*] (or longer, if mutually agreed in writing by the Parties) to object in writing to a given proposed New Product Decision after such New Product Decision has been proposed to the JDC, as applicable, on any basis, including that [\*\*\*].
- (c) In the event that a Party objects in writing to a given proposed New Product Decision as provided in Section 4.6.2(b), no later than [\*\*\*] [\*\*\*] after such New Product Decision has occurred with respect to a given Licensed Antibody or Licensed Product, such matter shall be discussed by the JDC, and such matter may be escalated for resolution as provided in Sections 2.8 and 13.1 if needed, to determine whether to approve such New Product Decision.
- (d) For clarity, if neither Party opposes a New Product Decision, then each Party's Independent Technology that falls within the definition of Alector Intellectual Property or GSK Intellectual Property, as applicable will be included within the definition of Alector Intellectual Property or GSK Intellectual Property, as applicable, without further action of the other Party or the applicable committee.

#### 4.7 Patient Samples.

**4.7.1** The Party conducting any Clinical Study shall retain and archive all patient samples (including any human biological material (and any derivative or progeny thereof), any portion of an organ, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative of such biological material such as stem cells or cell lines; and any human biological product, including, but not limited to, hair,

57

nail clippings, teeth, urine, faeces, breast milk, and sweat) collected and retained in connection with Clinical Studies involving a Licensed Antibody or Licensed Product that are performed under this Agreement and co-funded by the Parties (including those Clinical Studies conducted pursuant to Section 4.5.1(a)(i)) (together with appropriate compilations of Information with respect to such samples, "**Patient Samples**"). [\*\*\*].

- **4.7.2** Each Party agrees that any Patient Samples it collects in performance of activities under this Agreement will be obtained and will be stored, transferred, used and disposed of in accordance with all relevant Laws and any generally accepted and customary ethical guidelines regarding the collection, use, transport and disposal of human tissue.
- **4.7.3** Each Party agrees that it will seek all the relevant ethics committee approvals to enable the use of the Patient Samples obtained by or on behalf of such Party from patients or human subject volunteers or other donors in the Development of Licensed Antibodies or Licensed Products.
- **4.7.4** Each Party agrees that the use of Patient Samples by or on behalf of such Party in the activities under this Agreement will fall within the terms of the informed consent given by the donors of the samples or the clinical trial participants providing such samples. When a Party obtains samples from another entity that collected the samples outside the scope of activities conducted under the GDP, such Party shall obtain contractual confirmation that the entity complied with relevant requirements for informed consent, ethics committee/IRB approval and data privacy prior to such Party using such samples under this Agreement. Additionally, with respect to Patient Samples collected by a Party under this Agreement, each Party agrees, through the informed consent process, to seek to inform donors that (i) the research is being undertaken by a commercial entity, (ii) if applicable, the research involves the analysis of DNA and /or medical information, (iii) the Patient Samples may be transferred to a Third Party for testing, subsequent research use and storage purposes conducted for and on behalf of a commercial organization and its Third Party collaborators, and (iv) a commercial organization will have ownership of the results of the research performed on the Patient Samples and there will be no benefit whatsoever or any form of compensation for the donor in respect of the use of the Patient Samples by the commercial organization.
- **4.7.5** Each Party shall record each Patient Sample used or provided by it under this Agreement in a suitable Patient Sample level tracking system (the "**Tracking Records**"). Such Party shall maintain the Tracking Records at all points of the Patient Sample life cycle and including reporting on the status of each sample.
- **4.7.6** No human embryonic or fetal derived material (including cell lines) may be used in connection with a Party's activities under this Agreement without the express prior written approval of the other Party.

58

**4.7.7** In the event that a Party determines in its reasonable opinion that any informed consents for any clinical studies of a Licensed Product conducted by the other Party prior to the Effective Date or as part of the activities under the Agreement are insufficient to allow the transfer of Patient Samples or Personally Identifiable Information from such study to such Party or its Affiliates, then the other Party will use reasonable efforts to collaborate with such Party to agree upon an appropriate course of action to remedy such informed consent deficiencies and the other Party will take reasonable steps to carry out such agreed course of action to remedy such deficiencies, including to the extent agreed by such other Party, seeking a waiver or other approval from the applicable internal review boards for such study or, if agreed by the other Party, reconsenting patients.

#### **4.8** Progranulin Gene Therapy Program.

- **4.8.1** In the event Alector determines to [\*\*\*] (a "Gene Therapy Proposal"), along with a [\*\*\*]. Within [\*\*\*] ([\*\*\*]) [\*\*\*] after receipt of such Gene Therapy Proposal, GSK shall have the right to elect upon written notice, [\*\*\*] to include such Progranulin Gene Therapy in the definition of Licensed Products under this Agreement as further described below. Such election notice (including such payment) shall be referred to as the "Gene Therapy Opt-In Notice," and the date of such notice [\*\*\*] shall be referred to as the "Gene Therapy Opt-In Notice Date, the following shall apply:
- (a) The Parties shall negotiate and agree on an addendum to this Agreement ("Gene Therapy Addendum") setting forth the [\*\*\*] (such plan and budget, the "Gene Therapy GDP"). If the Parties are [\*\*\*]. The terms of any such addendum shall in any case, unless otherwise mutually agreed, provide for:
- (i) the same allocation of responsibility, decision-making and cost sharing for the Development and Commercialization of such Progranulin Gene Therapy as other Licensed Products under this Agreement;
- (ii) the same royalties, milestones and profit sharing for such Progranulin Gene Therapy as other Licensed Products under this Agreement, provided that [\*\*\*]; and

(iii) an [\*\*\*].

(b) The plan and budget submitted by Alector in the Gene Therapy Proposal shall be deemed to be the Gene Therapy GDP as of the Gene Therapy Opt-In Notice Date until the Gene Therapy Addendum is [\*\*\*] and Alector shall have the right to continue the Development of the Progranulin Gene Therapy pursuant to such plan and budget and the Parties shall share the Development Costs thereof in accordance with this Agreement (as if such Progranulin Gene Therapy was a Licensed Product and the Gene Therapy GDP (including budget therein) was the GDP and Development Budget). It is understood that the plan and budget in the Gene Therapy

59

Addendum (once agreed or established pursuant to Section 13.3.2) shall be the Gene Therapy GDP, but may subsequently be modified by the JDC to the same extent and in the same manner as the GDP may be modified.

- **4.8.2** For purposes of this Section 4.8, "**Progranulin Gene Therapy**" means [\*\*\*].
- **4.8.3** For clarity, it is understood and agreed that the opt-in right described in this Section 4.8 is a one-time right, exercisable only with respect to the first Progranulin Gene Therapy Proposal to be provided under this Section 4.8. Accordingly, if GSK does not provide a Gene Therapy Opt-In Notice as described above with respect to the first Gene Therapy Proposal provided by Alector hereunder, or withdraws its Gene Therapy Notice in accordance with Section 4.8.1(a) above, this Section 4.8 shall terminate and be of no force or effect, and thereafter Alector may Develop (including conduct IND enabling studies), Manufacture, Commercialize and otherwise exploit one or more Progranulin Gene Therapies independent of this Agreement without restriction or obligation to GSK, in the same manner and to the same extent as if this Section 4.8 did not exist. Unless and until GSK elects to include the Progranulin Gene Therapy as a Licensed Product in accordance with Section 4.8.1, (a) all Know-How and Patent rights made, generated or obtained by or on behalf of Alector or its Affiliates in performing activities with respect to a Progranulin Gene Therapy shall not be deemed Collaboration Intellectual Property, Collaboration Patents or Alector Intellectual Property and (b) GSK shall not have any right or license under any Know-How pertaining to a Progranulin Gene Therapy disclosed to GSK in connection with a Gene Therapy Proposal or under this Section 4.8.

# ARTICLE V COMMERCIALIZATION

#### **5.1** Commercialization Efforts.

- **5.1.1** <u>JCC Oversight</u>. The JCC shall oversee Commercialization of Cost Profit Sharing Products in the Field in the United States, provide a forum for communicating with respect to other Commercialization activities with respect to Licensed Products in the Territory, and perform such other functions with respect to Commercialization of Licensed Products as are provided for in Section 2.5.
- **5.1.2** Commercialization Principles. It is the intent of the Parties that Commercialization of Licensed Products will be conducted in accordance with the following principles, except to the extent (if any) otherwise expressly provided in the U.S. Commercialization Plan established in accordance with Section 5.3.1, 5.3.2, 5.3.5(a), or 5.3.5(b) (as applicable) in accordance with the Compliance Plan. The JCC shall take into account and implement the following principles in reviewing and providing input into the Global Strategic Launch Plan and in its decision-making, including in the preparation, review and approval of updates to the U.S. Commercialization Plan, and otherwise when allocating Commercialization responsibilities between the Parties in accordance with this Agreement:

60

- (a) The JCC shall serve as a conduit for sharing information, knowledge and expertise relating to the Commercialization of the Licensed Product. The principles of information-sharing with respect to Commercialization of the Cost Profit Sharing Products in the United States shall be reciprocal between the Parties, [\*\*\*].
- (b) In connection with Alector's role as Lead Party for Commercialization of Cost Profit Sharing Product for Non-AD/PD Minor Indications in the United States, Alector will [\*\*\*].
- (c) The U.S. Commercialization Plan shall include a meaningful role for both Parties for Cost Profit Sharing Products, as described in Section 5.1.3 and 5.8 below. In allocating responsibilities between the Parties, the JCC (or the JSC, or the Executive Officers, if applicable) shall take into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities, [\*\*\*] but in each case the allocation of activities shall at all times abide by the terms of this ARTICLE V.
- (d) The U.S. Commercialization Plan shall be established in a manner to optimize coordination and cooperation between the Parties with respect to Commercialization of the Cost Profit Sharing Products in the United States, while maintaining overall efficiency.
- (e) The Commercialization of Cost Profit Sharing Products in the U.S. and the U.S. Commercialization Plan shall be subject to, and in accordance with, the Compliance Program.

# 5.1.3 Overall Commercialization Responsibilities; Lead Parties.

- (a) Sales Booking of Cost Profit Sharing Products. GSK shall book all sales of Cost Profit Sharing Products [\*\*\*].
- (b) *Commercialization Activities for Cost Profit Sharing Products in the OUS Territory.* GSK shall be responsible for all Commercialization activities with respect to Cost Profit Sharing Products in the OUS Territory.
- (c) *United States*. Subject to Section 5.1.3(a) above, responsibility for Commercialization activities in the United States for Cost Profit Sharing Products shall be allocated as follows:
- (i) *Major Indications*: Subject to Sections 5.1.3(d), 5.7 and 5.8 below, GSK shall be the Lead Party for conducting Commercialization activities with respect to Cost Profit Sharing Products in the United States for all Major Indications and for all Indications for Parkinson's Disease and Alzheimer's Disease (i.e., both Major Indications and Minor Indications for Parkinson's Disease and Alzheimer's Disease) (the "**Major and Related Indications**").

61

- (ii) *Minor Indications*: Similarly, subject to Sections 5.1.3(d), 5.7 and 5.8 below, Alector shall be the Lead Party for conducting Commercialization activities with respect to Cost Profit Sharing Products in the United States for all Minor Indications other than the Major and Related Indications (the "**Non-AD/PD Minor Indications**").
- (d) *Remedial Actions*. The JCC shall review and discuss each Party's (and its Affiliates') performance of its obligations as Lead Party or Co-Promoting Party and if the JCC determines that a Party or its Affiliate has [\*\*\*]. [\*\*\*], then the non-breaching Party will provide written notice to the other Party and the JCOWG of the occurrence of any such event described above. Such notice (the "Non-Compliance Notice") will, in each case, expressly reference this Section 5.1.3(d), and reasonably describe the [\*\*\*] (such activities, "Offending Activities"), and will provide reasonable substantiation thereof.
- (i) The JCOWG shall meet on the [\*\*\*] following receipt of such notice and the Parties will reasonably cooperate, via the JCOWG, to expeditiously (and in any event with in [\*\*\*] [\*\*\*]) evaluate the [\*\*\*];
- (ii) If the Offending Activities are either substantiated by the JCOWG or the JCOWG is unable to reach consensus, the [\*\*\*];
- (iii) If the Offending Activities are [\*\*\*], then, within [\*\*\*] ([\*\*\*]) [\*\*\*], the breaching Party shall provide a [\*\*\*]. If the non-breaching Party does not agree to [\*\*\*].
  - (iv) If the breaching Party does not [\*\*\*].
- (e) *Lead Party Activities*. The designation as "**Lead Party**" means the applicable Party shall be responsible for the implementation of strategic and operational activities to Commercialize Cost Profit Sharing Product, as such activities pertain to the applicable Indication Category, including: [\*\*\*].
- (f) *Distribution*. Subject to the foregoing, and Section 5.7 below, GSK shall be responsible for distribution, warehousing, shipping, demand estimation, customer support, return management and processing, for all Indications of Cost Profit Sharing Products in the United States.
- (g) *Opt Out Products*. GSK and its Affiliates shall book all sales and be responsible for all Commercialization activities worldwide with respect to Opt Out Products, as further described in Section 5.1.4(c) below. Following the exercise by Alector of the Alector Opt Out, GSK shall replace Alector as the Lead Party with respect to Non-AD/PD Minor Indications for such Opt Out Product in the United States beginning no sooner than [\*\*\*] ([\*\*\*]) [\*\*\*] after the applicable Opt Out Notice Date, which period of time may be adjusted upon agreement by the

62

Parties, and the Parties shall cooperate fully to complete transition of such activities to GSK in a smooth and efficient manner as soon as reasonably practicable.

# 5.1.4 Activities and Participation.

- (a) Each Party shall use [\*\*\*] to execute and to perform, or cause to be performed, [\*\*\*]. Notwithstanding anything to the contrary contained herein, a Party or its Affiliate shall not be obligated to undertake or continue any Commercialization activities with respect to the Licensed Antibodies or Licensed Products if such Party (or Affiliate) reasonably determines that performance of such Commercialization activity would violate applicable Law or if such Commercialization activities with respect to the applicable Licensed Antibody or Licensed Product would pose an unacceptable safety risk to patients.
- (b)\_With respect to the OUS Territory, unless otherwise agreed by GSK and Alector, GSK will implement and will have sole authority and responsibility for the Commercialization of Cost Profit Sharing Products in the Field in the OUS Territory, [\*\*\*].
- (c) In the event Alector exercises an Alector Opt Out with respect to one or more Opt Out Products, unless otherwise agreed by GSK and Alector, GSK will implement and will have sole authority and responsibility for the Commercialization of the Opt Out Products in the Field in the United States and the OUS Territory, in each case in accordance with the Opt Out Commercialization Plan, the Global Strategic Launch Plan and the terms of this Agreement. GSK shall [\*\*\*] Commercialize such Opt Out Products for each Indication after Regulatory Approval is obtained for such Indication [\*\*\*].
- (d)\_Each Party and its Affiliates shall perform all Commercialization activities with respect to Licensed Products, in the United States and in the OUS Territory, in compliance with applicable Law, including all Health Care Laws and current standards for pharmacovigilance practice and, in accordance with the Compliance Program.

#### 5.2 Manner of Performance.

#### 5.2.1 Right to Subcontract Commercialization Activities.

(a) *Required Subcontract Terms*. Subject to Section 5.2.1(b), each Party and its Affiliates may [\*\*\*]. The JCC shall oversee the performance of Subcontractors under Material Subcontracts with respect to the Commercialization of Cost Profit Sharing Products in the United States in the same manner and to the same extent as its oversight of the Parties hereunder. Notwithstanding the foregoing, the subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Subcontractors with the applicable provisions of this Agreement.

63

- (b) Alector may engage a Third Party subcontractor to provide Sales Representatives to conduct Detailing and Medical Affairs activities solely in accordance with the terms set forth in this Section 5.2.1(b). Alector shall not [\*\*\*] without the prior written consent of GSK. Prior to executing an agreement with a Third Party subcontractor that will perform Detailing and/or Medical Affairs activities on behalf of Alector hereunder, Alector will (a) provide GSK with an opportunity to review and comment on the material terms, (b) ensure that such agreement includes all of the requirements and obligations of this Section 5.2.1 and the Compliance Program, including compliance, use of materials, training obligations, and ability to terminate upon Alector Opt Out, and (c) require the Third Party subcontractor to comply with the Compliance Program. Upon execution of any such contract with such Third Party subcontractor, Alector will provide GSK with a copy of such agreement.
- (c) *Obligation to Discuss.* Notwithstanding the foregoing, if either Party (or its Affiliate) desires to subcontract any of its assigned Commercialization activities with respect to the Commercialization of Cost Profit Sharing Products in the United States, such Party shall first discuss it with the other Party and take into account and reasonably consider amending the U.S. Commercialization Plan to reallocate such activities to the other Party or alternatively, subcontracting such activities to the other Party (at a cost to be agreed between the Parties), taking into account (balanced with other factors, including the principles prescribed in Section 5.1.2 above) the capabilities of the other Party and potential impact on costs, as a potential alternative to subcontracting such activities to a Third Party. In the event that any Commercialization activity allocated to either Party under the U.S. Commercialization Plan is subcontracted to the other Party (as opposed to being allocated to the other Party under the U.S. Commercialization Plan), then if the subcontracting Party remains ultimately responsible under this Agreement for the conduct of such activities, the other Party shall conduct such activities under the management of, and as directed by, the subcontracting Party, consistent with the terms of this Agreement and all applicable Laws.
- **5.2.2** <u>Day-to-Day Responsibility</u>. Each Party shall be responsible for day-to-day implementation of the Commercialization activities with respect to the Cost Profit Sharing Products for which it has or otherwise is assigned responsibility under this Agreement or the U.S. Commercialization Plan and shall keep the other Party reasonably informed as to the progress of such activities. Each of the Parties may appoint a single U.S. Commercialization alliance manager to be responsible for the day-to-day coordination of such Commercialization activities in the United States contemplated by this Agreement and the U.S. Commercialization Plan.
- **5.2.3** <u>Commercialization Standards</u>. Without prejudice to the Compliance Program, [\*\*\*]. The Parties may review and discuss each Party's (and its Affiliates') performance against such standards at each meeting of the JCC. If the JCC determines that a Party or its Affiliate has failed to comply with such standards and such failure could adversely affect the Development or Commercialization of any Licensed Product in the Field, or if the JCC does not agree and one

64

Party believes such is the case, the JCC shall (or such Party may) so notify the JSC and the JSC shall [\*\*\*].

#### **5.2.4** Commercialization Reports.

(a) Cost Profit Sharing Products in the United States. At each meeting of the JCC, each Party will report on the Commercialization activities such Party and its Affiliates have performed or caused to be performed with respect to Cost Profit Sharing Products in the United States since the last meeting of the JCC, evaluate the work performed in relation to the goals of the U.S. Commercialization Plan and provide such other information as may be required by the U.S. Commercialization Plan or reasonably requested by the JCC with respect to such Commercialization activities. If a Party fails to adequately provide such report at a meeting of the JCC, [\*\*\*]. The JCC shall evaluate each Party's and its Affiliates' performance during each Calendar Quarter in which Commercialization activities with respect to the Cost Profit Sharing Products in the Field are performed in the United States against the U.S. Commercialization Plan and provide a report of such progress to the JSC at least [\*\*\*] [\*\*\*], unless agreed otherwise by the Parties.

(b) *OUS Territory and Opt Out Products*. At each meeting of the JCC, GSK shall (i) [\*\*\*] (ii) provide [\*\*\*] with respect to Opt Out Products since the last meeting of the JCC.

#### **5.3** Commercialization Plans.

**5.3.1** <u>Global Strategic Launch Plan.</u> GSK shall develop and periodically update, and submit to the JSC for review and discussion, a written document describing the global product strategy for Commercialization of the Cost Profit Sharing Products in the Field in the U.S. and OUS Territory (the "**Global Strategic Launch Plan**"). The Global Strategic Launch Plan will include [\*\*\*]; provided however that the Global Strategic Launch Plan will not include any U.S. strategic implementation matters for Non-AD/PD Minor Indications in the United States without Alector's agreement. GSK will consider in good faith any comments of Alector or the JSC with respect to the Global Strategic Launch Plan, but such Global Strategic Launch Plan shall be approved solely by GSK. The Commercialization of the Cost Profit Sharing Products in the Field in the United States shall be governed by the U.S. Commercialization Plan, which shall be generally consistent with the strategies set out in the Global Strategic Launch Plan. The initial Global Strategic Launch Plan shall be developed and submitted to the JSC for review within the [\*\*\*] [\*\*\*] period prior to anticipated First Commercial Sale in the Territory, and shall be completed and approved by GSK, after consideration in good faith of any comments of Alector or the JSC, no later than [\*\*\*] [\*\*\*] prior to anticipated First Commercial Sale of a Cost Profit Sharing Product in the Territory.

**5.3.2** <u>U.S. Commercialization Plan</u>. The Parties shall cooperate to develop, the JCC shall review, and the JSC shall review and approve, a U.S. Commercialization Plan for Cost Profit Sharing Products that sets forth the Commercialization activities to be undertaken with respect to Cost Profit Sharing Products in the Field in the United States The U.S. Commercialization Plan

65

shall at all times be consistent with the Global Strategic Launch Plan and Section 5.1.3 above. The joint Commercialization of the Cost Profit Sharing Products in the Field in the United States shall be governed by the U.S. Commercialization Plan, which shall allocate such Commercialization activities between the Parties in accordance with the terms of this Agreement, including the principles set forth in Section 5.1.2 and the provisions of Sections 5.1.3 (and if applicable, Section 5.8 below). Unless otherwise determined by the JCC, the U.S. Commercialization Plan shall be a [\*\*\*] [\*\*\*] rolling plan, updated annually as provided in Section 5.3.5(b). The initial U.S. Commercialization Plan shall be submitted to the JCC for review no later than [\*\*\*] prior to anticipated First Commercial Sale in the United States, and submitted to the JSC for approval no later than [\*\*\*] [\*\*\*] prior to anticipated First Commercial Sale in the United States. The U.S. Commercialization Plan shall include [\*\*\*]. The terms of and activities set forth in the U.S. Commercialization Plan shall at all times be designed to be in compliance with all applicable Laws and the Compliance Program.

**5.3.3** <u>U.S. Commercialization Budget</u>. The U.S. Commercialization Budget included in the U.S. Commercialization Plan shall be a rolling [\*\*\*] [\*\*\*] budget setting forth the budgeted amounts for costs with respect to activities allocated to the Parties under the U.S. Commercialization Plan during the then-current Calendar Year and the successive [\*\*\*] Calendar Years thereafter, and shall include for both Parties a budget for FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter for the then-current Calendar Year. The U.S. Commercialization Budget shall also include [\*\*\*] as determined by the JCC in conjunction with the Finance Working Group. Concurrently with the annual preparation of the U.S. Commercialization Plan in accordance with Section 5.3.5(b), the JCC shall also prepare, and the JSC shall review to approve, an updated U.S. Commercialization Budget covering the next Calendar Year and the succeeding [\*\*\*] [\*\*\*].

**5.3.4** If Alector exercises an Alector Opt Out for one or more Opt Out Products, GSK shall develop a plan for the Commercialization of such Opt Out Products in the Field in the Territory (the "**Opt Out Commercialization Plan**"). The Commercialization of Opt Out Products in the Field in the Territory shall be governed by the Opt Out Commercialization Plan. GSK will have responsibility for determining strategy and overall guidelines regarding the marketing, market access, Medical Affairs, and sales for Opt Out Products in the Field in the Territory, and development of Promotional Materials and Packaging for the Opt Out Products.

#### 5.3.5 Amendments and Updates.

(a) <u>Global Strategic Launch Plan</u>. GSK shall develop, and submit to the JSC for review and discussion, an annual update to the Global Strategic Launch Plan. Such update shall be developed and submitted to the JSC no later than [\*\*\*] of the prior Calendar Year. After consideration in good faith of any comments of Alector or the JSC, such updated Global Strategic Launch Plan shall be completed and approved by GSK and shall take effect on the first day of the Calendar Year to which such Global Strategic Launch Plan applies. [\*\*\*]. Upon approval by GSK (after consideration in good faith of any comments of Alector or the JSC), the Global

66

Strategic Launch Plan shall be amended accordingly. For clarity, pursuant to Section 5.3.1, the Global Strategic Launch Plan shall not be amended to include any U.S. strategic implementation matters for Non-AD/PD Minor Indications in the U.S. without Alector's agreement. [\*\*\*].

(b) U.S. Commercialization Plan. The Parties shall cooperate to develop, and submit to the JCC for review, an updated [\*\*\*] [\*\*\*] rolling plan for Commercializing the Cost Profit Sharing Products in the United States for each Calendar Year (and the [\*\*\*] [\*\*\*]), which shall include an updated U.S. Commercialization Budget for such [\*\*\*] [\*\*\*] period. The JCC shall submit each such U.S. Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur no later than [\*\*\*] of the prior Calendar Year. Upon the JSC's preliminary approval, such plan shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [\*\*\*] of the prior Calendar Year, and after final approval by the JSC, such U.S. Commercialization Plan shall take effect on the first day of the Calendar Year to which such U.S. Commercialization Plan applies. The JCC shall review each Party's (and its Affiliates') performance under the U.S. Commercialization Plan (including the U.S. Commercialization Budget) on a [\*\*\*] basis, and shall develop detailed and specific updates and substantive amendments to the U.S. Commercialization Plan that reflect such performance. The JCC shall also reasonably consider any proposed updates and amendments to the U.S. Commercialization Plan presented by either Party. The JSC shall review such proposed amendments presented by the JCC and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon such approval by the JSC, the U.S. Commercialization Plan shall be amended accordingly. Amendments and updates to the U.S. Commercialization Plan, including the U.S. Commercialization Budget, shall not be effective without the approval of the JSC or the Executive Officers pursuant to Section 13.1, or determination pursuant to Section 13.3, as applicable. In the event that the JSC does not approve an updated U.S. Commercialization Plan, including the U.S. Commercialization Budget, prior to the start of the next Calendar Year, either Party may initiate procedures to resolve the issue pursuant to Sections 13.1 and 13.3, and the then-current U.S. Commercialization Plan, together with the budgeted amounts set forth in the [\*\*\*] [\*\*\*] rolling U.S. Commercialization Budget, shall continue to apply until the U.S. Commercialization Plan is agreed by the JSC or determined pursuant to Section 13.1 or Section 13.3.

(c) Opt Out Commercialization Plan. GSK shall review with the JCC and JSC annually, the then-current version of the Opt Out Product Commercialization Plan, no later than [\*\*\*] of the prior Calendar Year.

# 5.4 Medical Affairs Responsibilities.

<u>5.4.1 OUS Territory</u>. During the Term, GSK, either itself or by and through its Affiliates, Sublicensees or subcontractors, will be solely responsible for all Medical Affairs activities with respect to the Licensed Products throughout the OUS Territory and Opt Out Products in the U.S., at GSK's sole cost and expense, in accordance with the Global Strategic Launch Plan and Exhibit

67

<u>5.4.2 United States</u>. The Party to which a particular Medical Affairs activity is allocated under a U.S. Commercialization Plan will lead the performance thereof, and, [\*\*\*] and in compliance with the Compliance Program. If a particular Medical Affairs activity is allocated to both Parties to perform jointly under the U.S. Commercialization Plan, then both Parties will conduct such activity in collaboration with each other. Each Party will use reasonable efforts in the U.S. to cobrand all sponsorships, booths, and similar activities to the extent related to the Cost Profit Sharing Products and such cobranding is permitted under applicable Law. Each Party will conduct all Medical Affairs activities in the U.S. in accordance with the U.S. Commercialization Plan, the Compliance Program, and as otherwise agreed by the JCC (and set forth in writing (which may include minutes of the applicable JCC meeting) and approved by the JSC as needed).

5.4.3 Medical Affairs Materials. In accordance with Section 2.6.4, the JCOWG will establish an appropriate working group for the medical, legal and regulatory review of all Medical Affairs Materials (the "MLR Working Group"). The MLR Working Group will have representatives from both Parties with appropriate expertise to carry out the responsibilities of the MLR Working Group. The Lead Party for an Indication Category [\*\*\*] in accordance with the U.S. Commercialization Plan and the Compliance Program. All such Medical Affairs Materials will be submitted to the MLR Working Group for review and approval, and such MLR Working Group will serve as the review and approval committee for all Medical Affairs Materials to be used by either Party in the U.S. following the GSK Medical Affairs procedural processes for approval of such materials. The Lead Party for the applicable Indication Category will be [\*\*\*] to applicable Regulatory Authorities for comments or approval as required. [\*\*\*]. Neither Party shall use any materials other than the Medical Affairs Materials that have undergone the review and approval process set forth in this Section 5.4.3 for use in connection with the conduct of Medical Affairs activities related to the Licensed Products under this Agreement. In addition, neither Party will be required to use any Medical Affairs Materials that its own internal compliance team has not also approved. The Lead Party shall be responsible for providing and shipping to the other Party all Medical Affairs Materials in quantities necessary for such Party to perform its activities under the U.S. Commercialization Plan.

**5.4.4** Medical Affairs Training. The Lead Party for an Indication Category shall [\*\*\*] the training programs and materials relating to Medical Affairs activities for the Cost Profit Sharing Product ("Medical Affairs Training Materials") for use in the United States with respect to the Indication Category for which such Lead Party is responsible for the Parties' Medical Affairs activities, in each case consistent with applicable Law, the U.S. Commercialization Plan and the Compliance Program. All such Medical Affairs Training Materials will be submitted to the MLR Working Group for review and approval in accordance with the process outlined above in Section 5.4.3 for the review of Medical Affairs activities. [\*\*\*]. The Medical Affairs Training Materials will be updated annually taking into account any areas identified through internal monitoring of activities by each Party for enhanced or refreshed training. Following the initial training of Medical Affairs personnel, [\*\*\*], regular training programs for its own Medical Affairs personnel

68

using the most up-to-date Medical Affairs Training Materials. Each Party shall have the right to join the other Party's Medical Affairs trainings and provide input. For the avoidance of doubt, the Medical Affairs Training Materials will include training on applicable aspects of the Compliance Program. [\*\*\*]. Each Party shall be responsible for the performance of its own Medical Affairs representatives.

## 5.5 Advertising and Promotional Materials for Cost Profit Sharing Products.

5.5.1 United States. The Lead Party for an Indication Category shall [\*\*\*] (collectively, "Promotional Materials"), for use in the United States with respect to the Indication Category for which such Lead Party is responsible, in each case consistent with applicable Law, U.S. Commercialization Plan and the Compliance Program. In accordance with Section 2.6.4, the JCOWG will establish an appropriate Working Group for the medical, legal and regulatory review of all Promotional Materials (the "PRC Working Group"). The PRC Working Group will have representatives from both Parties with appropriate expertise to carry out the responsibilities of the Working Group. The PRC Working Group shall be responsible for the medical, regulatory and legal review and approval of all Promotional Materials and for the interpretation and adherence to applicable Law and the requirements of the Compliance Program governing the preparation and use of such Promotional Materials. All Promotional Materials will be submitted to the PRC Working Group for review and approval, and such PRC Working Group will serve as the copy approval committee for the review and approval for all Promotional Materials to be used by either Party in the U.S. following the GSK copy approval procedural processes for approval of such materials. Lead Party will be solely responsible for any advance review of the Promotional Materials required by the applicable Regulatory Authority. [\*\*\*]. Neither Party shall use any promotional materials other than the Promotional Materials that have undergone the foregoing approval process for use in connection with the Commercialization and Detailing of the Cost Profit Sharing Products in the U.S. In addition, neither Party will be required to use any Promotional Materials that its own internal compliance team has not also approved.

**5.5.2** <u>OUS Territory and Opt Out Products</u>. GSK shall have sole responsibility for developing and approving Promotional Materials for use in the OUS Territory (and in the United States for Opt Out Products) by GSK and its Affiliates that comply with GSK's SOPs and applicable Laws and Regulatory Approvals and are consistent in all material respects with the Global Strategic Launch Plan. Copies of all Promotional Materials used by GSK in the OUS Territory (and in the United States for Opt Out Products) will be archived by GSK in accordance with applicable Laws. [\*\*\*].

# 5.6 Product Packaging.

The JCC shall develop and approve Cost Profit Sharing Product packaging for use in the United States, which shall be consistent with the U.S. Commercialization Plan, the Global Strategic Launch Plan and applicable Laws and Regulatory Approvals. GSK shall have sole responsibility for developing and approving Licensed Product packaging for use in the OUS Territory (and the United States for Opt Out Products) by GSK and its Affiliates, that shall be compliant with GSK's

69

applicable SOPs and applicable Laws and Regulatory Approvals and consistent in all material respects with the Global Strategic Launch Plan.

## 5.7 Sales and Distribution.

#### 5.7.1 United States.

### (a) Booking Sales.

- (i) *Cost Profit Sharing Products*. GSK and its Affiliates shall book all sales of Cost Profit Sharing Products in the United States [\*\*\*]. If Alector receives any orders for a Cost Profit Sharing Product in the United States, it shall refer such orders to GSK.
- (ii) *Opt Out Products*. GSK and its Affiliates shall book all sales of Opt Out Products in the United States, and shall be responsible for warehousing and distributing the Opt Out Products in the United States, and the allocation of responsibilities and activities under the U.S. Commercialization Plan [\*\*\*]. If Alector receives any orders for an Opt Out Product in the United States, it shall refer such orders to GSK.
- (b) <u>Pricing Matters</u>. GSK shall (i) [\*\*\*]; (ii) determine whether [\*\*\*]; and (iii) establish [\*\*\*]. GSK shall keep the JCC reasonably informed of pricing and reimbursement matters in the U.S. with respect to Cost Profit Sharing Products and shall consider in good faith the comments of, the JCC with respect to such matters.

## 5.7.2 OUS Territory.

- (a) <u>Booking Sales</u>. GSK and its Affiliates shall book all sales of Licensed Products in the OUS Territory, and shall be responsible for warehousing and distributing the Licensed Products in the OUS Territory. If Alector receives any orders for a Licensed Product in the OUS Territory, it shall refer such orders to GSK.
- (b) <u>Pricing Matters</u>. GSK shall have the responsibility for determining all list prices and overall pricing and discounting strategy for the Cost Profit Sharing Products in the OUS Territory, [\*\*\*].

## **5.8** Co-Promotion of Cost Profit Sharing Products in the United States.

**5.8.1** Co-Promotion. Alector shall have the right to provide up to fifty percent (50%) of the Detailing efforts for Major and Related Indications ("Alector's Co-Promote Right"), and GSK shall have the right to provide up to fifty percent (50%) of the Detailing efforts for Non-AD/PD Minor Indications, in each case with respect to Cost Profit Sharing Products in the United States, all in accordance with this Section 5.8 and the U.S. Commercialization Plan. Each such

70

Party conducting Detailing efforts for an Indication Category for which the other Party is the Lead Party is referred to below as the "Co-Promoting Party".

**5.8.2** Inclusion in U.S. Commercialization Plan. The JCC shall discuss and determine [\*\*\*] and such details shall be reflected in the U.S. Commercialization Plan which shall also include the tactical plan to implement such co-Detailing arrangement, including the allocation of Details for the applicable Indications to Co-Promoting Party and measures to coordinate such Detailing efforts (and if a U.S. Commercialization Plan has already been prepared, it shall be updated to include the foregoing as promptly as reasonably practicable). In each such case, the U.S. Commercialization Plan shall provide for a fair and reasonable allocation between the Parties of Detailing activities, [\*\*\*] and the like with respect to the applicable Cost Profit Share Product and Indication Category, and each party shall use [\*\*\*] to perform the Details so allocated to it pursuant to such U.S. Commercialization Plan. If the JCC cannot agree on the foregoing matters, (a) with respect to Non-AD/PD Minor Indications [\*\*\*], and (b) with respect to any other indications [\*\*\*].

**5.8.3** Adjustment of Percentage. Notwithstanding Section 5.8.2, the Co-Promoting Party shall have the right to adjust the percentage of Details it will provide pursuant to Section 5.8.1 from time to time, subject always to a maximum of [\*\*\*] ([\*\*\*]), by so notifying the other Party at least [\*\*\*] ([\*\*\*]) [\*\*\*] prior to the time such adjustment will take effect, with the limitation that any such adjustment shall only take effect as of [\*\*\*] of the applicable Calendar Year. Once the Co-Promoting Party has so adjusted such percentage, it shall not again adjust the percentage for a period of [\*\*\*] [\*\*\*] (i.e., any such subsequent adjustment shall not take effect prior to the [\*\*\*] anniversary of such prior adjustment). The Co-Promoting Party shall not reduce the percentage of Details it will provide pursuant to this Section 5.8 with respect to a Cost Profit Sharing Product to zero (or to any percentage less than [\*\*\*] ([\*\*\*])) without the prior written approval of the other Party.

## 5.9 Training.

The Lead Party shall [\*\*\*] the initial Licensed Product training programs and materials ("**Product Training Materials**") for use in the United States with respect to the Indication Category for which such Lead Party is responsible, [\*\*\*] and in each case consistent with applicable Law, the U.S. Commercialization Plan and the Compliance Program. All such Product Training Materials will be submitted to the PRC Working Group for review and approval. The Lead Party shall conduct such training programs for all Sales Representatives prior to the launch of the applicable Cost Profit Sharing Product; *provided* that thereafter each Party shall be responsible for, and shall conduct, training programs using the most up-to-date Product Training Materials for its own Sales Representatives who will participate in Detailing the Cost Profit Sharing Product using the Product Training Materials to ensure a consistent, focused promotional strategy between the Parties that is consistent with the Approved Labeling for the applicable Cost Profit Sharing Product. The Product Training Materials will be updated annually taking into account any areas identified through internal monitoring of activities by each Party for enhanced or refreshed training. For the

71

avoidance of doubt, the Product Training Materials [\*\*\*].

## 5.10 Management of Sales Representatives.

Each Party will be responsible [\*\*\*], and will provide a sufficient number of full time employees to serve as district managers for such purposes and may, but will not be obligated to, designate one (1) or more full time employees to serve as regional directors having the responsibility for supervising a group of its district managers in a particular geographic region of the United States. The U.S. Commercialization Plan shall include [\*\*\*]. Nothing in this Agreement shall be construed to conclude that any of a Party's Sales Representatives or any other agents or employees of such Party are agents or employees of the other Party or subject to such other Party's direction and control. Each Party shall [\*\*\*]. Any and all Detailing performed by a Party hereunder shall be tracked using such Party's internal recording of such activity; provided that such tracking [\*\*\*] will be shared at the JCC for review and discussion to measure compliance with each Party's obligations under the U.S. Commercialization Plan.

## **5.11** Other Responsibilities.

- **5.11.1** <u>United States</u>. GSK shall be responsible for handling all returns of the Cost Profit Sharing Products in the United States, and if a Cost Profit Sharing Product sold in the United States is returned to Alector, Alector shall promptly ship such Cost Profit Sharing Product to a facility designated by GSK. GSK shall also be responsible for handling all aspects of Cost Profit Sharing Product order processing, invoicing and collection, distribution, inventory and receivables in the United States.
- **5.11.2** OUS Territory and Opt Out Products. GSK shall be responsible for handling all returns of the Licensed Products in the OUS Territory and Opt Out Products, and if a Licensed Product sold in the OUS Territory or Opt Out Product sold in the United States is returned to Alector, Alector shall promptly ship such Licensed Product to a facility designated by GSK. GSK shall also be solely responsible for handling all aspects of order processing, invoicing and collection, distribution, inventory and receivables for Licensed Products in the OUS Territory and Opt Out Products in the United States.
- **5.12** <u>Adverse Event and Product Complaint Reporting Procedures; Notice of Information Affecting Marketability of the Licensed Product.</u>
- **5.12.1** Pharmacovigilance Agreement. The Parties shall meet to negotiate in good faith and agree on processes and procedures for sharing pharmacovigilance data for the Parties to comply with Pharmacovigilance regulatory obligations and applicable Laws, prior to a Clinical Study by GSK for a Licensed Product. The agreed-upon processes and procedures shall be set forth in a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") containing mutually agreed terms and conditions that are customary for agreements of this type.

72

**5.12.2** Global Safety Database. Until the commencement of a Clinical Study by GSK for a Licensed Product under the GDP, Alector shall maintain a global safety database of adverse events and pregnancy reports for such Licensed Product, which shall be used for regulatory reporting and responses to safety queries from Regulatory Authorities by both Parties. Reasonably prior to the commencement of a Clinical Study by GSK for a Licensed Product under the GDP, Alector shall transfer such global safety database for such Licensed Product to GSK and thereafter, GSK shall maintain, and be responsible for, the global safety database for such Licensed Product, provided that upon Alector's request GSK shall provide [\*\*\*].

## 5.13 Recalls, Market Withdrawals or Corrective Actions.

In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product in the United States or in the OUS Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the United States or the OUS Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, shall within [\*\*\*] hours, advise the other Party thereof by telephone or email. GSK, in consultation with Alector, shall decide whether to conduct a recall of a Cost Profit Sharing Product in the United States (except in the case of a government mandated recall, when GSK may act without such advance notice but, shall notify Alector as soon as possible) and the manner in which any such recall shall be conducted (and in the event of any disagreement regarding a recall in the United States, the approach that is more conservative shall control). GSK shall decide, in its sole discretion, whether to conduct a recall in any country in the OUS Territory of a Licensed Product, or in the United States of an Opt Out Product, and shall have sole discretion to determine the manner in which any such recall shall be conducted. Each Party will make available to the other Party, upon request, all of such Party's (and its Affiliates') pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall. The costs and expenses of any such recall in the United States for a Cost Profit Sharing Product shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in the Financial Exhibit.

### **5.14** Medical Inquiries.

The Lead Party with respect to an Indication Category shall [\*\*\*] hours of receipt and shall respond to all inquiries from the Lead Party and follow the directives of the Lead Party in connection therewith. GSK shall handle all medical questions or inquiries from members of the medical profession in the OUS Territory regarding the Licensed Products and in the United States regarding Opt Out Products and Alector shall, and shall cause its Field Based Representatives to, refer to GSK all such questions and inquiries within [\*\*\*] hours of receipt and shall respond to all inquiries from GSK and follow the directives of GSK in connection therewith. [\*\*\*].

### 5.15 Early Access Programs.

73

[\*\*\*]. If [\*\*\*] desires to undertake an Early Access Program with respect to a Cost Profit Sharing Product in the United States, such Party shall submit (a) [\*\*\*] (b) [\*\*\*]. If the JDC and JMC agree to an Early Access Program proposal, such proposal shall be submitted to the JSC for review and approval. The JSC shall approve such Early Access Program proposal unless the JSC determines in good faith that the proposed Early Access Program [\*\*\*]. Any Early Access Program conducted by either Party for the Cost Licensed Products shall be in accordance with the plan therefor to the extent established by the JDC. [\*\*\*].

# **5.16** Field Based Representatives.

- **5.16.1** Each medical representative or medical science liaison used by a Party or its Affiliate to perform in-person presentations of the Cost Profit Sharing Products to health care professionals, or to perform sales calls (each, a "**Field Based Representative**" and each of those performing detailing, a "**Sales Representative**"), in the United States pursuant to this Agreement shall be employed by such Party or one of its Affiliates on a full-time basis (or engaged by such Party or one of its Affiliates as an independent contractor in his or her individual capacity) as a member of its field force for the relevant Indication(s) or hospital-based field force that visits targeted prescribers.
- **5.16.2** In the event that during the first [\*\*\*] [\*\*\*] following First Commercial Sale of a Cost Profit Sharing Product in a country, [\*\*\*].
- **5.16.3** Alector and GSK shall each ensure that its and its Affiliates' Sales Representatives do not make any representation, statement, warranty or guaranty with respect to the Licensed Product that is not consistent with the Approved Labelling for a Licensed Product for the applicable country, including mutually approved limited warranty and disclaimers, if any. Alector and GSK shall each ensure that its and its Affiliates' Sales Representatives do not make any statements, claims or undertakings to any person with whom they discuss or promote the Licensed Products that are not consistent with, nor provide or use any labeling, literature or other materials other than, those Promotional Materials currently approved for use by the PRC Working Group in the United States. If at any time the PRC Working Group no longer approves the use of specified Promotional Materials in the United States, each Party shall immediately take action to remove the Promotional Materials from use by its and its Affiliates' Sales Representatives in the United States and destroy such materials.
- **5.16.4** Alector and GSK shall each cause its and its Affiliates' Field Based Representatives to comply with applicable Laws related to the performance of its obligations hereunder, including the Drug Regulation Laws, the Federal and State Anti-Kickback Statutes and all applicable regulations thereunder, the AMA and PhRMA Guidelines, and all relevant EMA regulations, authorizations and local laws regarding advertisement, sale and promotion of pharmaceutical products as well as any relevant code of practice.

74

**5.16.5** Each Party shall, and shall cause its Affiliates to, maintain records of its Field Based Representative activities in the United States and each Party shall allow, and shall cause its Affiliates to allow, representatives of the other Party to inspect such records upon request during normal business hours and upon reasonable prior notice.

#### 5.17 Compliance.

**5.17.1** The Parties will comply with their respective obligations under the Compliance Program established pursuant to Exhibit 5.17.1 in relation to the Commercialization of Cost Profit Sharing Products in the U.S. In the event that Alector is unwilling or unable to comply with its obligations in the Compliance Program, Alector shall have the option, in its sole discretion, to terminate its role as a Lead Party or Co-Promoting Party upon [\*\*\*] ([\*\*\*]) [\*\*\*] notice to GSK (it being understood that such termination shall not be deemed an Alector Opt-Out).

# ARTICLE VI MANUFACTURE AND SUPPLY

### 6.1 Manufacture.

- **6.1.1** <u>JMC Oversight; Efforts</u>. The JMC, in consultation with the JDC and the Finance Working Group, shall oversee and have authority regarding CMC Development, establishment of Manufacturing sources and supply chains, and Manufacture of Licensed Antibodies and Licensed Products in the Field, both in the United States and in the OUS Territory, subject to the provisions of this ARTICLE VI. Each of Alector and GSK shall use Commercially Reasonable Efforts to [\*\*\*].
- **6.1.2** <u>Manufacturing Principles</u>. The following shall apply with respect to the Manufacture of Licensed Antibodies and Licensed Products in accordance with this Agreement:
- (a) The Manufacture of each Licensed Product under this Agreement for the United States and the OUS Territory shall be conducted using a single, harmonized Manufacturing process, utilizing a single global formulation for such Licensed Product, except to the extent that the JMC approves Manufacturing process differences between manufacturing sites or approves differences between Licensed Products for different countries. The Parties anticipate they will attempt to improve continuously any such Manufacturing process and that the JMC will plan to establish at least [\*\*\*] Manufacturing sources for each Licensed Product.
- (b) Alector shall have responsibility for Manufacture of Licensed Antibodies and Licensed Products using Manufacturing Subcontractor(s) during the Initial Manufacturing Period and thereafter, GSK shall have responsibility for Manufacture of Licensed Antibodies and Licensed Products in accordance with the terms of this ARTICLE VI itself and/or through one or more Manufacturing Subcontractor(s) and Alector shall have the right to obtain supply of Licensed Antibodies and Licensed Product from GSK (as described in Section 6.4

75

below). In the event that GSK does not supply Licensed Antibodies and Licensed Product to Alector, GSK shall permit Alector to obtain Licensed Antibodies and Licensed Products directly from such Manufacturing Subcontractor(s) for the purpose of exercising its rights and performing its responsibilities under Sections 3.1, 3.2, 3.9.1 and ARTICLE IV, provided that in such case, it shall be Alector's sole responsibility to negotiate and enter into contracts directly with such Manufacturing Subcontractors and GSK shall have no liability with respect to the same. Furthermore, in no event shall Alector's contracts with such Manufacturing Subcontractors interfere with such Manufacturing Subcontractor's ability to perform its obligations to GSK. As used herein, the "Initial Manufacturing Period" means the period beginning on the Effective Date and ending on completion of Manufacturing Transfer.

- (c) The Parties shall reasonably cooperate, under the oversight and management of the JMC, to accommodate forecasting and/or timelines for advance ordering in connection with the Manufacture of Licensed Antibodies and Licensed Product.
- (d) Licensed Products used in Clinical Studies shall in each case be subject to release by the Party conducting the Clinical Study, and if the Party conducting the Clinical Study was not responsible for Manufacturing such Licensed Products, then the other Party shall use Commercially Reasonable Efforts to assist the Party conducting the Clinical Study in the determination of such release.
- (e) Alector has entered into the contracts listed on Exhibit 6.1.2(e) with Third Party contract manufacturers in connection with the Manufacture of Licensed Antibodies and Licensed Products (the "Existing Manufacturing Contracts"). During the Initial Manufacturing Period, the Parties will reasonably cooperate to oversee CMC Development activities and to perform the Manufacturing Transfer (subject to oversight and management of the JMC as set forth herein). During the Initial Manufacturing Period, (i) GSK will use Commercially Reasonable Efforts to assist Alector in overseeing the Manufacture and supply of Licensed Antibodies and Licensed Products under the Existing Manufacturing Contracts and in resolving Manufacturing issues, if any, that arise in connection therewith, and (ii) Alector will keep GSK fully informed of the status of Manufacturing activities undertaken by Alector's Manufacturing Subcontractors and will reasonably consider all advice and suggestions by GSK in connection with such Manufacturing activities. Following the Initial Manufacturing Period, GSK will keep Alector fully informed of the status of Manufacturing activities undertaken by GSK and GSK's Manufacturing Subcontractors, and will reasonably consider all advice and suggestions by Alector in connection with such Manufacturing activities.
- (f) Notwithstanding anything to the contrary in this Agreement, GSK acknowledges that Alector has not granted GSK the right to: [\*\*\*].
- **6.1.3** Right to Subcontract Manufacturing Activities. Each Party is permitted to use one or more of its Affiliates to perform its Manufacturing activities undertaken in accordance with this Agreement or any Supply and Quality Agreement. Neither Party (nor their Affiliates) may

76

subcontract to a Third Party the performance of any Manufacturing activities undertaken in accordance with this Agreement or any Supply and Quality Agreement, other than by Alector under an Existing Manufacturing Contract (a "Manufacturing Subcontract"), except in accordance with the following terms and conditions:

- (a) Neither Party (nor their Affiliates) may subcontract any of its obligations with respect to the oversight and management of Manufacturing activities under the GDP, the U.S. Commercialization Plan, or its participation on the JMC.
- (b) Before entering into a Manufacturing Subcontract with a Third Party, the subcontracting Party (or Affiliate of a Party) shall first notify the JMC of the Manufacturing activities to be subcontracted, the name of the proposed Third Party subcontractor and information regarding such Third Party's relevant experience and qualifications and the proposed fees or costs to be paid to such Third Party. The JMC shall be given a reasonable opportunity to review and discuss the proposal. If, following such discussion, a Party (or its Affiliate) still desires to subcontract the performance of Manufacturing activities hereunder to one or more Third Parties, it may proceed to do so, subject to compliance with this Section 6.1.3(b) and provided further that [\*\*\*] any transfer of GSK Manufacturing Know-How to such Third Party shall require the prior written consent of GSK, not to be unreasonably withheld. Prior to entering into any Manufacturing Subcontract which the subcontracting Party or its Affiliate anticipates at time of execution will entail payments to the Subcontractor in excess of [\*\*\*] or the use of GSK Manufacturing Know-How with respect to subcontracted Manufacturing activities under this Agreement (a "Material Manufacturing Subcontract"), the subcontracting Party shall [\*\*\*].
- (c) Neither Party (nor its Affiliates) will enter into a Manufacturing Subcontract with a Third Party that has been debarred, or is subject to debarment, pursuant to Section 306 of the FFDCA, or that is the subject of a conviction described in such section.
- (d) Each Manufacturing Subcontract with a Third Party must be in writing. A Third Party subcontractor who is a party to a Subcontract is referred to in this Agreement as a "Manufacturing Subcontractor" with respect to the particular Manufacturing activities covered by such Subcontract. Neither Party, nor their Affiliates, shall enter into any Manufacturing Subcontract with respect to Licensed Antibodies or Licensed Products after the Effective Date except in compliance with the terms of this Section 6.1.3. Each such Subcontract entered into after the Effective Date shall contain terms consistent with the terms and conditions of this Agreement, and shall contain reasonable and customary confidentiality and non-use provisions and provide GSK the right to enforce such confidentiality and non-use provisions in the event that the Manufacturing Subcontractor is an Approved CMO and will receive GSK Manufacturing Know-How. In addition, unless otherwise agreed to by the Parties and subject to Section 6.1.2(b), each such Manufacturing Subcontract entered into after the Effective Date shall grant the subcontracting Party a royalty-free, worldwide, sublicenseable license under any Know-How or Patents used by the Subcontractor to Manufacture the Licensed Antibody or Licensed Products, and the subcontracting Party shall use reasonable efforts to obtain a requirement in each Manufacturing

77

Subcontract for the Manufacturing Subcontractor to permit, and reasonably cooperate to facilitate, the transfer of any such Know-How between the Parties or their Affiliates or designated Third Party contract manufacturers (subject to the restrictions in Section 6.1.3(b) with respect to the transfer or disclosure of GSK Manufacturing Know How). The JMC shall have the right to oversee the performance of Manufacturing Subcontractors, and each Party shall have the right, based on reasonable cause, to request that the other Party audit the performance of the Manufacturing Subcontractors of such other Party and its Affiliates in accordance with the terms of the relevant Manufacturing Subcontract.

(e) The subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Affiliates and Subcontractors with the applicable provisions of this Agreement.

**6.1.4** Manufacturing Requirements. The JMC may develop and approve, standards applicable to the Parties' and their Affiliates' performance of Manufacturing activities in accordance with this Agreement or any Supply and Quality Agreement. Each Party (and their Affiliates) shall perform each such Manufacturing activity it undertakes in accordance with the applicable standards approved by the JMC. The Parties may review and discuss each Party's (and its Affiliates') performance against such standards at each meeting of the JMC. If the JMC determines that a Party or its Affiliate has failed to comply with such standards and such failure could adversely affect the Development or Commercialization of any Licensed Product in the Field, or if the JMC does not agree and one Party believes such is the case, the JMC shall (or such Party may) so notify the JSC and the JSC shall discuss whether any remedial action shall be taken.

## **6.2** Manufacturing Transfer.

Alector shall transfer responsibility for Manufacture of Licensed Antibodies and Licensed Products to GSK or GSK's nominated Manufacturing Subcontractor, and provide GSK or its Manufacturing Subcontractor with reasonable assistance and Alector Know-How pertaining to the Manufacture of Existing Antibodies and Existing Products, ("Manufacturing Transfer") in accordance with the manufacturing transfer plan, which shall be in accordance with the principles set out in Exhibit 6.2 (the "Manufacturing Transfer Plan"), which Manufacturing Transfer may occur at different times for the Existing Products (e.g., Manufacturing Transfer of AL001 may occur later than Manufacturing Transfer of AL101). The Manufacturing Transfer Plan shall be reviewed and approved by the JMC within [\*\*\*] ([\*\*\*]) [\*\*\*] after the JMC is established, and may be amended from time to time by the JMC, provided that in all cases the Manufacturing Transfer Plan shall minimize the risk of disruption to the supply of Existing Antibody and Existing Products for use in any Phase III Clinical Study. All such technology transfer and related communication shall be overseen and facilitated by the JMC. Alector shall provide (or cause to be provided by its relevant Affiliates or subcontractors) to GSK or its Manufacturing Subcontractor a reasonable level of technical assistance and consultation to support such Manufacturing Transfer and provide reasonable assistance with the qualification of the GSK or Manufacturing

78

Subcontractor's Manufacturing facility/ies with applicable Regulatory Authorities, all in accordance with the Manufacturing Transfer Plan.

# 6.3 CMC Development.

Responsibility for performing CMC Development for each Licensed Antibody and Licensed Product (and each formulation and dosage form thereof) shall be allocated under the GDP, provided that until the Manufacturing Transfer to GSK for an Existing Antibody and Existing Product, CMC Development shall be allocated to Alector and, to the extent any ongoing CMC Development activities as of such Manufacturing Transfer are to be transferred to GSK the Manufacturing Technology Transfer Plan shall provide for a plan for the transfer of such CMC Development activities. Each Party shall participate, through its representatives on the JMC, in decision-making with regard to CMC Development activities related to new formulations or dosage forms for Licensed Products and of associated Manufacturing processes, which activities shall be conducted in accordance with the approved GDP.

## **6.4** Supply and Quality Agreement.

If during the Term, a Party ("Non-Manufacturing Party") requires Licensed Antibody or Licensed Product for the conduct of activities under the GDP (or in the case of Alector, any Independent ADA or is requested pursuant to Section 6.1.2(b)) and at such time the other Party ("Manufacturing Party") is responsible for Manufacturing such Licensed Antibody or Licensed Product, then the Manufacturing Party shall supply such Licensed Antibody or Licensed Product to the Non-Manufacturing Party at Supply Cost and, upon either Party's request, the Parties shall enter into separate supply and associated quality agreements (each, a "Supply and Quality Agreement") covering the terms of such supply to such Party for such activities (and to the extent requested by the Party receiving such supply, (a) the Manufacturing Party shall cooperate to enter into such quality agreement on reasonably and customary terms for a quality agreement and (b) such quality agreement shall be entered into prior to such supply). The Supply and Quality Agreement will contain terms and conditions that are reasonable and customary for agreements of such nature. The terms of any such Supply and Quality Agreement, including the Manufacturing Party's and the Non-Manufacturing Party's respective rights and obligations under such Supply and Quality Agreement, shall be consistent with, and limited by, rights and obligations of the Manufacturing Party under any applicable Manufacturing Subcontract.

## **ARTICLE VII**

#### FINANCIAL PROVISIONS

#### 7.1 <u>Upfront Payment</u>.

In partial consideration of the rights granted to GSK under this Agreement, GSK shall make the following non-refundable, non-creditable payments: (a) \$500,000,000 to Alector within [\*\*\*]

79

[\*\*\*] of receipt of a valid invoice from Alector following the Effective Date and (b) \$200,000,000 to Alector within [\*\*\*] [\*\*\*] of receipt of a valid invoice from Alector on or after the [\*\*\*] [\*\*\*] of the Calendar Year following the Calendar Year in which the Effective Date is.

## 7.2 Milestone Payments.

**7.2.1** <u>Clinical Study Milestones</u>. GSK shall make the non-refundable, non-creditable payments to Alector set forth below in accordance with Section 7.2.4 upon the occurrence of the corresponding milestone event set forth below (each, a "Clinical Study Milestone"):

Milestone Event	Payment	
	Minor Indication	Major Indication
[***]*	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

<sup>\*</sup> For the avoidance of doubt, no Clinical Study Milestone shall be payable in respect of the Phase III Clinical Study for FTD-GRN Initiated by Alector prior to the Effective Date [\*\*\*].

Each Clinical Study Milestone shall be payable one time only, even if such Clinical Study Milestone occurs for a given Indication with respect to more than one Licensed Product (including Combination Products). Upon filing of an MAA in the U.S. or in any Major European Country or in the EMA Territory based on efficacy data from a Clinical Study, such Clinical Study shall be deemed a "Phase III Clinical Study" for purposes of this Section 7.2.1, and the corresponding milestone payment under this Section 7.2.1 with respect to such Clinical Study, if not previously paid, shall become due.

**7.2.2** <u>Approval Milestones</u>. GSK shall make the non-refundable, non-creditable payments to Alector set forth below in accordance with Section 7.2.4 upon the occurrence of the corresponding milestone event set forth below (each, an "**Approval Milestone**"):

80

Milestone Event	Payment	
	Minor Indication	Major Indication
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Each Approval Milestone shall be payable one time only, even if such Approval Milestone occurs for a given Indication with respect to more than one Licensed Product (including Combination Products).

**7.2.3** <u>Commercial Milestones</u>. GSK shall make the non-refundable, non-creditable payments to Alector set forth below in accordance with Section 7.2.4 upon the occurrence of the corresponding milestone event set forth below (each, a "Commercial Milestone"):

Milestone Event	Payment
[***]	[***]
[***]	[***]

81

Each Commercial Milestone shall be payable one time only, even if such Commercial Milestone occurs for a given Indication with respect to more than one Licensed Product (including Combination Products).

## 7.2.4 Milestone Payment Terms.

- (a) GSK shall notify in writing promptly, but in no event later than [\*\*\*] ([\*\*\*]) [\*\*\*] each achievement by GSK of a Clinical Study Milestone or Approval Milestone. Alector shall invoice GSK promptly following receipt of the foregoing notice or upon achievement of a Clinical Study Milestone or Approval Milestone. GSK shall pay all such Clinical Study Milestones and Approval Milestones due in U.S. Dollars within [\*\*\*] ([\*\*\*]) [\*\*\*] of GSK's receipt of the foregoing invoice from Alector.
- (b) GSK shall notify Alector in writing promptly, but in no event later than [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of the Calendar Quarter in which the achievement of each Commercial Milestone occurs. GSK shall pay all such Commercial Milestone a payments due in U.S. Dollars within [\*\*\*] ([\*\*\*]) [\*\*\*] GSK's receipt of an invoice from following the achievement of the corresponding milestone event.

## **7.2.5** Certain Milestone Matters. [\*\*\*]

### 7.3 U.S. Pre-Tax Profit or Loss.

- **7.3.1** Sharing of Pre-Tax Profit or Loss. Subject to Section 7.3.2, the Parties shall share in Pre-Tax Profit or Loss in the United States as follows: Alector shall bear (and be entitled to) 50%, and GSK shall bear (and be entitled to) 50%.
- **7.3.2** <u>Alector Commercialization Opt Out</u>. If Alector provides an Alector Opt Out pursuant to Section 4.5.5, then following the Alector Opt Out Date, Alector shall not be entitled to receive (or be obligated to pay) any share of the Pre-Tax Profit or Loss with respect to the applicable Opt Out Product, and shall, instead receive royalties on Net Sales for the Opt Out Product pursuant to Section 7.4.2.

## 7.4 OUS Territory Royalties and Opt Out Product Royalties.

**7.4.1** Royalty Rate. During the Royalty Term of this Agreement, GSK shall pay royalties, on a Licensed Product-by-Licensed Product basis, to Alector on the annual, aggregate Net Sales of each Licensed Product in the OUS Territory at the applicable royalty rates set forth below:

82

Annual Aggregated Net Sales of a Licensed Product in OUS Territory	Royalty Rate
On the portion of annual Net Sales less than [***] Million U.S. Dollars ([***])	[***]
On the portion of annual Net Sales equal to or greater than [***] Million U.S. Dollars ([***])	[***]
but less than [***] Million U.S. Dollars ([***])	
On the portion of annual Net Sales equal to or greater than [***] Million U.S. Dollars ([***])	[***]

For purposes of this Section 7.4.1, any Licensed Product incorporating the same Licensed Antibody as another Licensed Product shall be considered the same Licensed Product for purposes of calculation of annual aggregated Net Sales in the above table such that the Net Sales of all Licensed Products incorporating the same Licensed Antibody are aggregated.

Further and for clarity, once the Royalty Term for a Licensed Product has expired in a given country in the OUS Territory, Net Sales for such Licensed Product in such country will not be included in the calculation of aggregate annual Net Sales used to determine the royalty rate for such Licensed Product.

Additionally, if the Royalty Term for a Licensed Product continues with respect to some, but not all Indications, then the Finance Working Group shall establish mechanisms to track and allocate the Net Sales of such Licensed Product between the applicable Indications (e.g., between all Co-Funded Indications for which the Royalty Term continues on the one hand and all other Indications on the other hand), which may include engaging Third Parties to provide services or information to assist in doing so (e.g., [\*\*\*] to provide an estimated sales of Licensed Product by Indication). To the extent a Third Party is so engaged, the Out-of-Pocket Costs paid to such Third Party shall be borne by GSK and treated as a Third Party Payment.

**7.4.2** <u>Adjustment in Event of Alector Opt Out</u>. Notwithstanding Section 7.4.1 above, in the event Alector exercises an Alector Opt Out with respect to a Licensed Product:

(a) the royalty payment obligation under Section 7.4.1 shall apply to Net Sales of each Opt Out Product in the U.S. subject to the remainder of this Section 7.4.2 (with the Net Sales tiers for calculating the royalty with respect to the Opt Out Product being the same as set forth in Section 7.4.1 (i.e., up to [\*\*\*], [\*\*\*] and over [\*\*\*])), but such Net Sales amounts shall instead be Net Sales of the Opt Out Product in the United States (instead of the OUS Territory); and

(b) if Alector funds its share of Development Costs (as described in Section 4.5.1(a)(iii) above) for at least one Phase III Clinical Study for the Opt Out Product, each royalty rate set forth in the table under Section 7.4.1 (i.e., [\*\*\*], [\*\*\*] and [\*\*\*]) in respect of Net Sales

83

in the U.S. for such Opt Out Product shall be increased by adding to such rate an amount equal to [\*\*\*] multiplied by a fraction, the numerator of which is [\*\*\*], and the denominator of which is [\*\*\*].

- (i) "Phase III and Later Development Costs" means, [\*\*\*].
- (ii) For purposes of calculating the increase in the royalty rates set forth in the table under Section 7.4.1 (such increase, the "**Incremental Royalty**"): [\*\*\*].
- **7.4.3** Know-How Royalties. The amounts owing by GSK under this Agreement are attributable independently but concurrently to the Patent licensed to GSK hereunder, as well as the grant of other rights and undertakings of each of the Parties in this Agreement (including rights to Know-How, Collaboration Intellectual Property and the restrictions on each Party's activities in Sections 3.5 and 3.6). However, if it is determined in a legal proceeding with respect to this Agreement that amounts to be paid hereunder with respect to Licensed Products not covered by an issued and unexpired patent of Alector or its Affiliates must be subject to a further reduction to be valid and enforceable, then such amounts shall be reduced by the minimum amount necessary to make such payment obligations valid and enforceable.

## 7.4.4 Reductions. Notwithstanding the foregoing:

- (a) in any calendar quarter during the Royalty Term, on a country-by-country and Licensed Product-by-Licensed Product basis, such Licensed Product [\*\*\*] then the royalty payable under Section 7.4.1 shall be reduced by [\*\*\*] for such Licensed Product in such country during any calendar quarter [\*\*\*].
- (b) without limiting Section 7.4.4(a) above, in the event that in any country or other jurisdiction in the OUS Territory (or the United States with respect to an Opt Out Product) [\*\*\*] with respect to a Licensed Product then, for each such country or other jurisdiction, the royalties payable to Alector for the Net Sales of such Licensed Product in such country or other jurisdiction shall be reduced by [\*\*\*] for such Licensed Product in such country during any Calendar Quarter [\*\*\*].
- (c) in the event that GSK or Alector enters into an agreement with a Third Party pursuant to Section 7.7 in order to obtain a license or right under Blocking Third Party Technology owned or controlled by such Third Party for a particular country or other jurisdiction in the OUS Territory (or the United States for an Opt Out Product) [\*\*\*] GSK shall be entitled to deduct from any royalties payable under this Section 7.4 with respect to such Licensed Product in such country or other jurisdiction in a Calendar Quarter [\*\*\*] paid to such Third Party or reimbursed to Alector, as the case may be, for such Blocking Third Party Technology [\*\*\*].

84

(d) in the event, on a Licensed Product-by-Licensed Product basis, [\*\*\*] then, subject to Section 7.4.4(e), the royalty rate to be paid to Alector under this Section 7.4 for such Calendar Year shall be reduced by [\*\*\*].

(e) notwithstanding anything in this Agreement to the contrary, under no circumstances shall the reductions set forth in this Section 7.4 cause the royalties payable to Alector with respect to a given Licensed Product in any country in the OUS Territory (or in the United States with respect to an Opt Out Product) in any Calendar Quarter to be reduced to less than [\*\*\*] of the amount that would otherwise be due (i.e., without giving effect to the reductions specified in this Section 7.4) with respect to such Licensed Product in such country in such Calendar Quarter.

## **7.5** Royalty Reporting and Payment.

Each Calendar Quarter following the First Commercial Sale of a Licensed Product in the OUS Territory (or in the U.S. for an Opt Out Product), GSK shall furnish to Alector a written report showing on a Licensed Product—by—Licensed Product and country-by-country basis (a) the Net Sales, (b) all relevant exchange rate conversions in accordance with Section 7.14, (c) the calculation of the royalties payable under this Agreement on account of those Net Sales, and, to the extent applicable, (c) the calculation of any reductions pursuant to Section 7.4.4. enable the royalties payable to be determined and the information provided to be verified. Each royalty report along with the royalties payable for such Calendar Quarter are due and payable to Alector within [\*\*\*] ([\*\*\*]) [\*\*\*] following the end of such Calendar Quarter. All payments due under this Section 7.5 shall be made by bank wire transfer in immediately available funds to an account designated by Alector.

## **7.6** Quarterly Reconciliation and Payments.

**7.6.1 Procedure.** Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, deductions, reductions, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in this Agreement or the Financial Exhibit will be established by the Finance Working Group (together with the Development Reconciliation Procedures, the "**Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.

**7.6.2 Reporting.** Beginning on the date when either Party first incurs an Allowable Expense in accordance with this Agreement, within [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of each Calendar Quarter, each Party shall provide to the Finance Working Group a report of its calculation of actual Pre-Tax Profit or Loss with respect to such Cost Profit Sharing Product for such Calendar Quarter (each, a "**Financial Report**"), in such reporting format and detail as the Finance Working Group shall establish for use, which reporting format shall be consistent with the categories calculated by the reporting Party in accordance with its Accounting Standards; provided, however, that a preliminary estimate of the Allowable Expenses, in a format agreed by the Finance Working

85

Group, shall be provided by each of Alector and GSK by the [\*\*\*] ([\*\*\*]) [\*\*\*] of the [\*\*\*] ([\*\*\*]) [\*\*\*] of each Calendar Quarter for purposes of financial statement close process. Each Financial Report shall specify in reasonable detail any Net Sales, Other Income or Allowable Expenses or other amounts necessary to calculate Pre-Tax Profit or Loss for the United States or royalties for such Cost Profit Sharing Product in the corresponding Calendar Quarter received and incurred by the reporting Party or any of its Affiliates, Sublicensees or subcontractor in accordance with this Agreement in such Calendar Quarter. Following receipt of such Financial Report, each Party shall reasonably cooperate to provide additional information as necessary to permit calculation and reconciliation of Pre-Tax Profit or Loss for the United States and such royalties for the applicable Calendar Quarter, and to confirm that Allowable Expenses are in conformance with the approved U.S. Commercialization Budget.

**7.6.3 Flash Sales Reports.** As soon as reasonably practicable, but in no event later than the [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of each Calendar Quarter, on a Cost Profit Sharing Product-by-Cost Profit Sharing Product basis, beginning with the Calendar Quarter in which the First Commercial Sale of such Cost Profit Sharing Product occurs, GSK will provide to the Finance Working Group a flash report providing a good faith, non-binding estimate of Net Sales of such Cost Profit Sharing Product accrued during the respective Calendar Quarter. Alector will use reasonable efforts to limit the disclosure of such flash reports (to the extent corresponding to a period not publicly reported by GSK) to those Alector personnel that would have access to similar financial information of Alector's prior to public announcement thereof. The flash report may be based on forecasted numbers and the Parties agree that the final Net Sales reported in the Financial Reports for reconciliation may differ from these flash sales reports.

**7.6.4 Net Sales Reporting.** Without limiting the generality of Section 7.6.2 or Section 7.5, within [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of each Calendar Quarter, beginning with the first Calendar Quarter in which the First Commercial Sale of such Cost Profit Sharing Product in the U.S. occurs, GSK shall provide the Finance Working Group with a report of the Net Sales for the preceding Calendar Quarter on a Cost Profit Sharing Product-by-Cost Profit Sharing Product for the U.S. The Finance Working Group may agree from time-to-time on the form and level of detail of such report.

### 7.6.5 Reconciliation and Payment

(a) <u>Reconciliation Discussion</u>. In the event that either Party has any questions or concerns regarding the Development Costs (including with respect to Sections 4.5.3, 4.5.4(g)) or calculation of Pre-Tax Profit or Loss reported by the other Party in a Financial Report pursuant to this Section 7.6, the Finance Working Group shall endeavor to resolve such questions and concerns of either Party within [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of the Calendar Quarter in which such questions or concerns are raised. Additionally, the Finance Working Group may by mutual agreement adjust the timing for notification or payment of any reconciliation payments hereunder.

86

(b) Quarterly Reconciliation Payment. Unless such timing is otherwise modified by the Finance Working Group, within [\*\*\*] ([\*\*\*]) [\*\*\*] after receipt of each Party's Financial Report provided pursuant to this Section 7.6 or Section 4.5.3, the Finance Working Group shall confer and agree in writing on a reconciliation report setting out in reasonable detail the calculation of Pre-Tax Profit or Loss in the United States and royalties in the OUS Territory (and the United States with respect to Opt Out Products) and any payment to be paid by Alector to GSK or by GSK to Alector, as the case may be, ("Balancing Payment") in order to effect the sharing of Development Costs in accordance Section 4.5.4(g) and the sharing of Pre-Tax Profit or Loss in accordance with this Section 7.6 and payment of royalties in accordance with Section 7.5. Within [\*\*\*] ([\*\*\*]) [\*\*\*] of receipt of such report from the Finance Working Group, each Party that is owed a Balancing Payment shall invoice the other Party for the amount of the Balancing Payment due and the other Party shall pay such invoiced amount within [\*\*\*] ([\*\*\*]) [\*\*\*] after delivery of such invoice.

# 7.7 Blocking Third Party Technology.

If, during the Term, a Party determines, in its reasonable judgment, that it is necessary or desirable to obtain rights under any Blocking Third Party Technology in order to Develop, Manufacture or Commercialize the Licensed Product in the Field in accordance with this Agreement, said Party shall promptly notify the other Party, and the Parties shall discuss such matter, including whether a license under such Blocking Third Party Technology would be necessary or desirable, and discussion of which Party should obtain such a license, and upon request of either Party shall seek the advice of mutually agreed joint patent counsel and reasonably take into account such counsel's opinion. In the event that the Parties do not agree, the notifying Party or its Affiliate shall thereafter have the right to (i) obtain a sublicenseable license under such Blocking Third Party Technology from the relevant Third Party or (ii) acquire such Blocking Third Party Technology from the relevant Third Party, but such Blocking Third Party Technology shall not be included within the Alector Intellectual Property or GSK Intellectual Property, as the case may be. Any amounts paid to any Third Party to license or acquire any Blocking Third Party Technology in order to Develop, Manufacture or Commercialize a Licensed Antibody or Licensed Product shall [\*\*\*].

## 7.8 Existing Third Party Agreement Payments.

Payments under the Existing Third Party Agreements incurred after the Effective Date that are attributable and allocable to the activities undertaken by the Parties in accordance with this Agreement ("Existing Third Party Agreement Payments") shall (a) to the extent allocable to the United States for a Cost Profit Sharing Product, be included as Allowable Expenses in determining Pre-Tax Profit or Loss as provided in the Financial Exhibit and (b) to the extent allocable to the OUS Territory or the Opt Out Products for the United States: [\*\*\*] ("Royalty Territory Existing Third Party Agreement Payments"). To the extent an Existing Third Party Agreement Payment is not specific to the United States or the OUS Territory, or such Existing Third Party Agreement Payment is in support of a Cost Profit Sharing Product and Opt Out Products or other products, then the Finance Working Group shall allocate such Existing Third

87

Party Agreement Payment between the Cost Profit Sharing Products, Opt Out Products, and other products and between the United States and the OUS Territory. In the event that Alector proposes to terminate or reduce the amount of any Existing Third Party Agreement Payments by making a payment to the counter-party to such Existing Third Party Agreement, it shall first discuss such proposal with GSK; and if Alector in fact makes such a payment to terminate or reduce the amount of any Existing Third Party Agreement Payments (such payment, a "**Buy Out Payment**") and GSK does not agree, within [\*\*\*] [\*\*\*] after Alector notifies GSK that Alector has made such a Buy Out Payment, to [\*\*\*], then [\*\*\*].

### **7.9** <u>Audits</u>.

Each Party and its Affiliates shall keep complete and accurate records of the items underlying Development Costs, Allowable Expenses, Other Income, Net Sales, payments under Existing Third Party Agreements, Blocking Third Party Technology Costs and the other elements required to prepare the reports or calculate payments required by Sections 4.5.3, 4.5.4, 7.3, 7.4, 7.5, 7.6, 7.7 and 7.8 and the Reconciliation Procedures, and any other payments under this Agreement. Each Party will have the right, at its own expense and no more frequently than once in any [\*\*\*] ([\*\*\*]) [\*\*\*] period (except in the case of fraud), to have an independent certified public accountant, selected by such Party from nationally reputable accounting firms in the United States or the United Kingdom and reasonably acceptable to the other Party, review any such records of the other Party and its Affiliates in the location(s) where such records are maintained by the other Party or its Affiliates upon at least [\*\*\*] [\*\*\*] prior written notice and during regular business hours and under obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under Sections 4.5.4, 7.3, 7.4, 7.5, 7.6, 7.7 and 7.8 and the Reconciliation Procedures, and any other payments due under this Agreement, within the prior [\*\*\*] [\*\*\*] period. If the review of such records reveals that the other Party has failed to accurately report information pursuant to Section 4.5.3, 4.5.4, 7.3, 7.4, 7.5, 7.6, 7.7 and 7.8, or the Reconciliation Procedures, or make any payment (or portion thereof) required under this Agreement, then the other Party shall promptly pay to the auditing Party any underpaid amounts due under Sections 4.5.4, 7.3, 7.4, 7.5, 7.6, 7.7 and 7.8, or the Reconciliation Procedures, or otherwise due under this Agreement, together with interest calculated in the manner provided in Section 7.15. If any such discrepancies are an underpayment of amounts due under this Agreement, or overpayment of amounts reimbursed based on the other Party's invoice or reporting under this Agreement, in each case greater than [\*\*\*] ([\*\*\*]) of the amounts actually due for any Calendar Year the other Party shall pay all reasonable costs incurred in conducting such review. Once a Party has conducted a review and audit of the other Party pursuant to this Section 7.9 in respect of any given period, it may not subsequently re-inspect the other Party's or its Affiliates' records in respect of such period, unless a subsequent audit of a separate reporting period uncovers fraud on the part of the audited Party that is reasonably expected to have been occurring during the prior audited period. For clarity, however, if a discrepancy is identified by the accountant during the course of an audit and the Parties do not agree upon a resolution of such discrepancy, then the auditing Party's accountant

88

may re-inspect the books and records to the extent reasonably relevant to resolving such discrepancy.

## 7.10 Withholding Taxes.

- **7.10.1** Each Party will be responsible for all Taxes imposed on such Party's net income, or on net income allocated to such Party under applicable Law. Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes (as that term is defined in Section 7.10.5 below) except to the extent that any such deduction or withholding is required by law in effect at the time of payment.
- **7.10.2** Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the "**Payee**") to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax. Except as provided in Section 7.10.3, any such Tax, to the extent withheld and paid to the appropriate governmental authority, (a) shall be treated for all purposes of this Agreement as having been paid to the Payee, and (b) will be an expense of and borne by Payee.
- **7.10.3** Notwithstanding anything to the contrary in this Agreement, in the event that a Party redomiciles or assigns its rights or obligations in accordance with Section 14.1 (each, a "**Tax Action**"), and as a result of such Tax Action the amount of Tax required to be withheld under Section 7.10.1 in respect of a payment to another Party is greater than the amount of such Tax that would have been required to be withheld or paid absent such Tax Action, then any such amount payable shall be increased to take into account such withholding taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable), the Party receiving such payment receives an amount equal to the sum it would have received had no such increased withholding been made. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding Tax (i) would not have been imposed but for a Tax Action taken by the Party eligible to receive additional amounts pursuant to the preceding sentence or (ii) are attributable to the failure by the Party receiving a payment to comply with the requirements of Section 7.10.4. For purposes of this Section 7.10.3, a "redomiciliation" shall include a reincorporation or other action resulting in a change in tax residence of the applicable Party or its assignee.
- <u>7.10.4</u> Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Parties. The Parties will cooperate with respect to all documentation required by any applicable taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes.
- <u>7.10.5</u> For purposes of this Section 7.10, "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees in the nature of a tax (including interest, penalties and additions thereto).

89

# 7.11 Indirect Taxes.

All payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such payments following receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by the receiving Party in respect of those payments. The Parties shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes. If the Indirect Taxes originally paid or otherwise borne by the paying Party are in whole or in part determined to be refundable to the receiving Party (including by reason of not having been properly chargeable in the first instance), all reasonably necessary steps requested by the paying Party will be taken by the receiving Party to receive a refund of such Indirect Taxes from the applicable governmental authority or other fiscal authority and any amount of such Indirect Taxes repaid or refunded by such authority to the receiving Party (net of any amounts incurred with respect to the receipt of such amounts) will be transferred to the paying Party within [\*\*\*] ([\*\*\*]) [\*\*\*] of receipt. "Indirect Taxes" means any value added, sales, purchase, turnover or consumption tax as may be applicable in any relevant jurisdiction.

#### 7.12 Tax Matters.

**7.12.1** No Partnership. Nothing contained in this Agreement shall be deemed or construed by the Parties or any of their Affiliates, or any third person to treat the relationship between the Parties contemplated by this Agreement as a partnership, joint venture or other business entity under Treasury Regulations Section 301.7701-1(a)(2) (or any corresponding provision under state, local or non-U.S. tax Law) (an "**Entity**"). Without the prior written consent of the Parties (such consent not to be unreasonably withheld, delayed or conditioned), no Party (or successor or assignee) shall, for Tax purposes, report the relationships established by this Agreement as an Entity, including either (a) making any disclosure that the relationships established by this Agreement may give rise to an Entity (whether on a U.S. Internal Revenue Service Form 8275 or otherwise) or (b) withholding any amounts from payments made to the other Party pursuant to Section 1446 of the Code (or any corresponding provision under state, local or non-U.S. tax law), unless required by a tax authority on audit or other examination.

**7.12.2** <u>Cooperation on Inter-Party Structure</u>. Each Party shall cooperate in good faith if requested by the other Party to establish or facilitate an optimal inter-Party financial operational structure (including, if necessary, procedures and agreements among the various Affiliates of the Parties) which is consistent with the economic result contemplated herein, consistent to the extent feasible with each Party's internal structures and procedures, and not adverse to the Parties financial, economic, or tax positions.

### **7.13** Tax Information.

90

GSK shall use commercially reasonable efforts to provide information in GSK's or its Affiliate's possession, which is reasonably requested by Alector in order to determine or prove eligibility for the Foreign Derived Intangible Income deduction pursuant to Section 250 of the Internal Revenue Code of 1986 or any future deduction or credit that is substantially similar to such deduction or which provides for a similar information or proof requirement.

## 7.14 Currency Exchange.

<u>7.14.1 Currency of Payments</u>. All payments under this Agreement shall be paid in U.S. Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

7.14.2 Currency Conversion. For the purpose of calculating any amounts due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than U.S. Dollars), in the case of any amounts designated in another currency, each Party shall convert such foreign currency into U.S. Dollars using its standard conversion method consistent with applicable Accounting Standards in a manner consistent with the respective Party's customary and usual conversion procedures used in preparing its audited financial reports applied on a consistent basis, provided that such procedures use a widely accepted source of published exchange rates. With respect to Cost Profit Sharing Products, the Parties shall share equally (50/50) any Currency Gains and Losses as a result of such conversion. For the purposes of this Section 7.14.2, "Currency Gains and Losses" means the gain or loss resulting from changes in exchange rates between the functional currency and the foreign currency in which the transaction is denominated, to the extent specifically identifiable to a Cost Profit Sharing Product and shall only include the actual currency gains and losses realized between the end of a Calendar Quarter and the date of invoice payment for that Calendar Quarter.

## 7.15 Late Payments.

If either GSK or Alector shall fail to make a timely payment pursuant to Section 4.5, 7.1, 7.2, 7.3, 7.4 or any other provisions of this Agreement, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest at [\*\*\*], but in no event higher than the highest rate permissible under Law, effective for the first date on which payment was delinquent and calculated on the number of days such payment is overdue.

## 7.16 Resolution of Financial Disputes.

In the event there is a dispute, claim or controversy relating to any financial obligation by one Party to the other Party pursuant to this Agreement, such Party shall provide such other Party with a written notice setting forth in reasonable detail the nature and factual basis for such good-faith dispute and each Party agrees that it shall seek to resolve such dispute within [\*\*\*] [\*\*\*] of the date such written notice is received. In the event that no such resolution is reached by the Parties,

91

the dispute shall be resolved through the procedures set forth in Section 13.4 (except as for matters within the original authority of the Finance Working Group).

# ARTICLE VIII INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

**8.1** Ownership of Inventions.

- **8.1.1** <u>Sole Inventions</u>. Each Party (or its Affiliate) shall exclusively own all inventions conceived solely by such Party, its Affiliates or their employees, agents and consultants in the course of such Party's and its Affiliates' performance of Development, Manufacturing or Commercialization activities under this Agreement ("**Sole Inventions**"). Sole Inventions conceived solely by GSK or its Affiliates or any of their employees, agents and consultants are referred to herein as "**GSK Sole Inventions**". Sole Inventions conceived solely by Alector or its Affiliates or any of their employees, agents and consultants are referred to herein as "**Alector Sole Inventions**".
- **8.1.2** <u>Joint Inventions</u>. The Parties or their Affiliates shall jointly own all inventions conceived jointly by employees, agents and consultants of GSK or its Affiliates, on the one hand, and employees, agents and consultants of Alector or its Affiliates, on the other hand, in the course of performing Development, Manufacturing or Commercialization activities under this Agreement, on the basis of each Party having an undivided interest in the whole ("**Joint Inventions**"). [\*\*\*].
- **8.1.3** <u>Inventorship</u>. For purposes of determining whether an invention is a GSK Sole Invention, an Alector Sole Invention or a Joint Invention, questions of inventorship shall be determined in accordance with United States patent laws and as if the applicable activity were conducted in the United States.
  - 8.2 Prosecution and Maintenance of Patents Globally.

As between the Parties:

**8.2.1** Prosecution [\*\*\*]. Each Party agrees to use Commercially Reasonable Efforts to file [\*\*\*] and to reasonably cooperate, and to cause its Affiliates to cooperate, with the other with respect to the preparation, filing, prosecution and maintenance ("**Prosecution**") of [\*\*\*] pursuant to this Section 8.2.1. [\*\*\*].

8.2.2 [\*\*\*]

8.2.3 [\*\*\*]

92

## 8.3 Third Party Infringement.

Each Party shall promptly notify the other of any apparent, threatened or actual infringement by a Third Party of any [\*\*\*] by an Infringing Product of which it becomes aware.

- **8.3.1** Enforcement In the United States. [\*\*\*]
- **8.3.2** Enforcement Outside the United States. [\*\*\*]
- **8.3.3** Conduct of Biosimilar Patent Litigation. If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the United States Public Health Service Act ("PHSA") or equivalent in any other jurisdiction in the Territory (a "Biosimilar Application") naming a Licensed Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(l)(9)(C) of the PHSA), either Party shall, within [\*\*\*] ([\*\*\*]) [\*\*\*], notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA or equivalent in any other jurisdiction in the Territory. If either Party receives any equivalent or similar certification or notice in any other jurisdiction in the Territory, such Party shall, within [\*\*\*] ([\*\*\*]) [\*\*\*], notify and provide the other Party with copies of such communication. Regardless of the Party that is the "reference product sponsor" for purposes of such Biosimilar Application, [\*\*\*].
- **8.3.4** Cooperation. In any suit or enforcement action brought under the [\*\*\*] in any jurisdiction, each Party shall, and shall cause its Affiliates to, reasonably cooperate with each other, in good faith and shall agree to be a party to such suit, if necessary. Notwithstanding the above, neither Party shall settle or compromise any related defense or infringement suit brought pursuant to this Section 8.3 without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Furthermore, each Party shall provide the other Party with reasonable prior notice and opportunity to review and comment and shall consider in good faith all reasonable comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement and/or defense of any [\*\*\*].
- **8.3.5** Conduct of Certain Actions; Costs. The Party initiating suit shall have the right to select counsel, mutually acceptable to the Parties (approval of such counsel not to be unreasonably withheld, conditioned or delayed), for any suit initiated by it pursuant to this Section 8.3. If required under applicable Law in order for the initiating Party to initiate or maintain such suit, the other Party or its Affiliate shall join as a party to the suit. At the initiating Party's reasonable request, such other Party shall offer reasonable assistance to the initiating Party in connection therewith at no charge to the initiating Party. [\*\*\*].

93

- **8.3.6** <u>Recoveries</u>. With respect to any suit or action initiated pursuant to this Section 8.3, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:
- (a) first, the Parties shall be reimbursed for all costs incurred in connection with such proceeding paid by the Parties and not otherwise recovered, reimbursed or previously included in Shared Patent Costs (to the extent Infringing Product corresponds to a Cost Profit Sharing Product); and
  - (b) second, any remainder shall be:
- (i)\_with respect to a suit or action in the OUS Territory or related to an Infringing Product corresponding to an Opt Out Product, [\*\*\*] shall be allocated to the Party initiating the suit or action and [\*\*\*] to the other Party; and
- (ii) with respect to a suit or action related to an Infringing Product corresponding to a Cost Profit Sharing Products in the United States, shared in the ratio of [\*\*\*] to GSK and [\*\*\*] to Alector.

**8.3.7** [\*\*\*]

# 8.4 Patent Invalidity Claim.

## **8.4.1** Right to Respond. [\*\*\*]

**8.4.2** Conduct of Certain Actions; Costs. The non-controlling Party shall cooperate and shall be permitted to participate with the controlling Party in the preparation and formulation of a response to an Invalidity Claim, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. The controlling Party shall have the sole and exclusive right to select counsel for the response to such Invalidity Claim. The Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Invalidity Claim in the U.S. shall be included in an Allowable Expense as a Shared Patent Cost, and otherwise borne by the controlling Party. To the extent permitted under such proceeding, the non-controlling Party shall also have the right to participate and be represented relative to such proceeding by its own counsel at its own expense. The controlling Party shall not settle any Invalidity Claim in a manner that admits the invalidity or unenforceability of any [\*\*\*], or that requires a payment to the Third Party in respect of such Invalidity Claim, without the consent of the other Party, which consent shall not be unreasonably withheld. To the extent any amounts are paid to a Third Party in settlement of such Invalidity Claim in the U.S., the same shall be included in Allowable Expenses as a Shared Patent Cost, and otherwise borne by the controlling Party.

# **8.5** Claimed Infringement.

94

Each of the Parties shall promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by GSK or Alector or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture, Commercialization or use of any Licensed Antibody or Licensed Product (any such suit or other action referred to herein as an "Infringement Claim"). Each of the Parties shall also promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by GSK or Alector or any of their respective Affiliates or Sublicensees with respect to the practice of any Alector Intellectual Property, GSK Intellectual Property or Joint Invention that is not an Infringement Claim. In the case of any Infringement Claim, the Parties shall promptly, and within [\*\*\*] [\*\*\*] of written notice from either Party to the other thereof, discuss which Party shall control the response to such Infringement Claim, and if the Parties do not mutually agree upon which Party shall control, then the Party against whom the Infringement Claim is filed shall have the first right to control the defense and response to any Infringement Claim, provided that if such Party does not notify the other Party that it elects to control the defense and response to a particular Infringement Claim within [\*\*\*] [\*\*\*] after written notice thereof between the Parties, then the other Party shall have the right to control the defense and response to a such Infringement Claim. Upon the request of the Party controlling the response to the Infringement Claim, the other Party shall reasonably cooperate with the controlling Party at the controlling Party's expense in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation at its own expense. With respect to any Infringement Claim by a Cost Profit Sharing Product (and not any Opt Out Product) in the U.S., GSK shall bear [\*\*\*] and Alector shall bear [\*\*\*] of the damages or recovery obtained by the Third Party asserting such Infringement Claim, by settlement or otherwise and with respect to any other Infringement Claim asserted against a Party, subject to ARTICLE XI, such Party shall bear the damages or recovery awarded to or obtained by any Third Party asserting such Infringement Claim against such Party, by settlement or otherwise. The Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Infringement Claim in the U.S. for a Cost Profit Sharing Product shall be included in Allowable Expenses as a Shared Patent Costs. Subject to ARTICLE XI, the Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Infringement Claim for any Opt Out Product shall be borne by the Party incurring such Out-of-Pocket Costs.

**8.6** Patent Term Extensions. [\*\*\*]

- 8.7 Trademarks.
- **8.7.1** Retained Rights in Corporate Marks and Logos. Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names, logos and other trademarks.
- **8.7.2** <u>Product Trademarks</u>. The Licensed Product shall be promoted and sold, in accordance with the Global Strategic Launch Plan using the Product Trademarks unless any such

95

Product Trademark cannot be legally used to promote and sell the Licensed Product in a country, in which case an alternative Product Trademark (i) approved by the JCC in the United States (other than for an Opt Out Product) shall be used in such country or (ii) approved by GSK shall be used (a) in any country in the OUS Territory or (b) for any Opt Out Product in the United States. GSK (or its Affiliates, as appropriate) shall own and retain all rights to Product Trademark(s) in the Territory, and all goodwill associated therewith. GSK shall own rights to any Internet domain names incorporating the Product Trademark(s) or any variation or part of such Product Trademark(s) as its URL address or any part of such address. GSK will use Commercially Reasonable Efforts to establish, maintain and enforce the Product Trademarks during the Term. All costs of such establishment, maintenance and enforcement efforts (the "**Product Trademark Costs**") for the United States with respect to a Cost Profit Sharing Product shall be an Allowable Expense and shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in the Financial Exhibit and otherwise, shall be borne by GSK.

- **8.7.3** <u>Trademark License.</u> GSK hereby grants to Alector a royalty-free, fully paid up, co-exclusive license to use the Product Trademark(s) solely for the purpose of conducting Development and Commercialization activities with respect to Licensed Products in accordance with this Agreement.
- **8.7.4** Product Trademarks and Co-Branding. Unless otherwise agreed by the Parties, all packaging materials, labels and Promotional Materials relating to Licensed Products in the Field shall display the Product Trademark(s) and no other product-specific trademarks or branding. In addition, all such materials shall display the trade names (and logos, to the extent GSK's logo is displayed) of both GSK and Alector in equal size and prominence, to the extent permitted by applicable Law. The trade dress, style of packaging and the like with respect to each Licensed Product in the Field within the OUS Territory may be determined by GSK in a manner that is consistent with GSK's standard trade dress and style.
- **8.7.5** Trademark Quality Control. Each Party shall, and shall cause its respective Affiliates to, comply strictly with trademark style and usage standards approved by the JCC from time to time in connection with use of the Product Trademark(s); provided, however, that the applicable Party, and not the JCC, shall approve any such standards with respect to the trademark style or use of the corporate names or logos of either Party. Each Party shall, and shall cause its Affiliates to, at its own expense, submit a sample of each proposed use of the Product Trademark to the JCC for approval, which approval shall not be unreasonably withheld or delayed. In the event that either Party reasonably objects to a proposed usage of the Product Trademark(s) or the trademark style or use of the corporate names or logos of such Party, it shall give written notice of such objection to the other Party within [\*\*\*] [\*\*\*] of receipt by the JCC of such sample, specifying the way in which such usage of such Product Trademark(s), trademark style, corporate name or logo fails to meet the style, usage or quality standards for the Licensed Product or Product Trademark set forth in the first two sentences of this Section 8.7.5. If such other Party or its Affiliate wishes to use such sample, it must remedy the failure and submit further samples to the

96

JCC for approval (or the objecting Party for approval with respect to trademark style or use of the corporate names or logos of the objecting Party).

**8.7.6** Enforcement. In the event either Party becomes aware of any infringement of any Product Trademark by a Third Party, such Party shall promptly notify the other Party. GSK shall be responsible in its sole discretion for all such enforcement efforts, including the cost thereof, for infringements in the Territory, and such costs in the United States in respect of Cost Profit Sharing Products shall be included as an Allowable Expense as a Product Trademark Cost and recoveries in the United States shall be shared equally. Each Party shall keep the other reasonably informed of such efforts. Upon either Party's request, the other shall reasonably cooperate with the requesting Party in such enforcement efforts.

# ARTICLE IX CONFIDENTIALITY AND PUBLICITY

#### **9.1** Confidential Information.

During the Term and for a period of [\*\*\*] [\*\*\*] after any termination or expiration of this Agreement, each Party agrees to, and shall cause its Affiliates to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other Party. As used herein, "Confidential Information" means information of the disclosing Party or its Affiliates given to the other Party or its Affiliate. For purposes of this Agreement, all "Confidential Information" (as defined in the Prior CDA) that was disclosed by GSK or its Affiliate to Alector under the Prior CDA shall be deemed Confidential Information of GSK, and all "Confidential Information" (as defined in the Prior CDA) that was disclosed by Alector to GSK or its Affiliate under the Prior CDA shall be deemed Confidential Information of Alector. The restrictions on the disclosure and use of Confidential Information set forth in the first sentence of this Section 9.1 shall not apply to any Confidential Information that:

- **9.1.1** was known by the receiving Party or its Affiliate prior to disclosure by the disclosing Party or its Affiliate hereunder (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);
- **9.1.2** is or becomes part of the public domain through no fault of the receiving Party or its Affiliates in violation of this Agreement;
- **9.1.3** is disclosed to the receiving Party or its Affiliate by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has to the disclosing Party or an Affiliate thereof; or

97

**9.1.4** is independently developed by personnel of the receiving Party or its Affiliate without reliance on the Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence).

Notwithstanding the foregoing, each Party may use and disclose the other Party's Confidential Information as follows: (i) under appropriate confidentiality obligations substantially equivalent to those in this Agreement, to its Affiliates, licensees, permitted Sublicensees, contractors and any other Third Parties to the extent such use and/or disclosure is reasonably necessary to perform its obligations or to exercise the rights granted to it, or reserved by it, under this Agreement; (ii) to the extent such disclosure is authorized by the other Party and is reasonably necessary for filing or prosecuting patent applications claiming the Development, Manufacture or Commercialization of Licensed Antibodies or Licensed Products (such filing and prosecution to be conducted subject to applicable procedures set forth in Section 8.2); or (iii) to the extent such disclosure is reasonably necessary: (A) in complying with the terms of agreements with Third Parties related to the Licensed Antibodies or Licensed Products that exist as of the Effective Date; (B) in complying with the terms of agreements with Third Parties related to Licensed Antibodies or Licensed Products that are entered into after the Effective Date, provided that such agreements are entered into in compliance with the terms of this Agreement and, further provided that the provisions of such agreements requiring disclosure of the other Party's Confidential Information have been reviewed and approved by such other Party (such approval not to be unreasonably withheld); or (C) in prosecuting or defending litigation, complying with applicable Law, regulations or legal process, including the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange (including NASDAQ), conducting Clinical Studies hereunder with respect to a Licensed Product in the Field and in Regulatory Filings or other communications or submissions to Regulatory Authorities, or submitting information to tax or other governmental authorities. If either Party or any of its Affiliates is required to disclose Confidential Information of the other Party in the case of clause (iii) of the immediately preceding sentence, such Party shall provide prior notice of such intended disclosure to such other Party if possible under the circumstances and shall disclose only such Confidential Information of such other Party as is required to be disclosed.

## 9.2 Recipient Obligations.

Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants, advisors and Subcontractors, Sublicensees and sub-distributors, and to the employees, consultants, advisors and Subcontractors, Sublicensees and sub-distributors of the receiving Party's Affiliates who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 9.1, provided that Alector and GSK shall each remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants, advisors and Subcontractors, Sublicensees and sub-distributors, to treat

98

such Confidential Information as required under Section 9.1 (as if such Affiliates, employees, consultants, advisors and Subcontractors, Sublicensees and sub-distributors were Parties directly bound to the requirements of Section 9.1).

## 9.3 Confidential Terms.

Each Party agrees not to, and to cause its Affiliates not to, disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party and its Affiliates may disclose the terms of this Agreement: (i) to advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners or private investors, and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement; or (ii) to the extent necessary to comply with applicable Laws and court orders (including securities laws or regulations and the applicable rules of any public stock exchange); provided that in the case of paragraph (ii), the disclosing Party or its Affiliate shall promptly notify the other Party and (other than in the case where such disclosure is necessary, in the reasonable opinion of the disclosing Party's legal counsel, to comply with securities laws or regulations) allow the other Party a reasonable opportunity to intervene to protect the confidentiality of the information and oppose such disclosure and, to the extent allowable by law, to seek limitations on the portion of the Agreement that is required to be disclosed.

## 9.4 Publicity.

**9.4.1** <u>Initial Press Releases</u>. Upon the execution of this Agreement, the Parties shall issue a mutually agreed joint press release regarding the subject matter of this Agreement, including a description of the aggregate financial terms and value of the Agreement, substantially in the form attached hereto as <u>Exhibit 9.4.1</u>.

**9.4.2** Further Publicity. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Products in the Field and other activities in connection with this Agreement that may include information that is not otherwise permitted to be disclosed under this ARTICLE IX, and that may be beyond what is required by law, and each Party may make such disclosures from time to time in accordance with the procedures set forth below. Such disclosures may include achievement of milestones, significant events in the development and regulatory process, commercialization activities and the like. Except for the initial press releases described in Section 9.4.1, whenever a Party (the "**Requesting Party**") elects to make any such public disclosure, it shall first notify the other Party (the "**Cooperating Party**") of such planned press release or public announcement and provide a draft for review at least [\*\*\*] [\*\*\*] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Law, or by regulation or rule of any public stock exchange (including NASDAQ), with as much advance notice as possible under the circumstances if it is not possible to provide notice at least [\*\*\*] [\*\*\*] in advance); provided, however, that a Party may issue such press release or public announcement without such prior review by the other Party if (i) the

99

contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by the issuing Party, (ii) such press release or public announcement does not materially differ from the previously issued press release or other publicly available information, and (iii) such press release or public announcement does not contain the other Party's name. The Cooperating Party may notify the Requesting Party of any reasonable objections or suggestions that the Cooperating Party may have regarding the proposed press release or public announcement, and the Requesting Party shall reasonably consider any such objections or suggestions that are provided in a timely manner. The principles to be observed in such disclosures shall include accuracy, compliance with applicable Law and regulatory guidance documents, reasonable sensitivity to potential negative reactions of the FDA (and its foreign counterparts) and the need to keep investors informed regarding the Requesting Party's business.

#### 9.5 Publications.

**9.5.1** Global Publication Strategy. The JDC shall develop a global publication strategy for the Development and Commercialization activities related to the Licensed Antibodies and Licensed Products in the Field (the "Global Publication Strategy") that is consistent with the GDP, Global Strategic Launch Plan and the U.S. Commercialization Plan. The JDC may from time to time develop and submit to the JSC for approval, other proposed substantive amendments to the Global Publication Strategy. The JSC shall review such proposed amendments presented by the JDC and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon such approval by the JSC, the Global Publication Strategy shall be amended accordingly. The Parties acknowledge that Alector has entered into agreements with Third Parties prior to the Effective Date which permit such Third Parties to make publications regarding Licensed Antibodies or Licensed Products, and agree that the Global Publication Strategy shall reasonably accommodate the ability of such Third Parties to make such publications. Notwithstanding the foregoing (or Section 9.5.2 below), the Global Publication Strategy shall not be construed to limit a Party's rights to make disclosures pursuant to Section 9.4 above.

**9.5.2** <u>Approval of Publications</u>. The publication and presentation of the results of Development carried out on the Licensed Antibodies and Licensed Products in the Field shall be governed by the Global Publication Strategy, and the Parties agree to conduct their publication activities in accordance with the Global Publication Strategy. Prior to publishing or presenting the results of any Development activities related to the Licensed Antibodies or Licensed Products, each Party (the "**Publishing Party**") shall provide to the other Party (the "**Reviewing Party**") a copy of any proposed abstracts, manuscripts or summaries of presentations that such Publishing Party intends to publish or present ("**Proposed Publications**"). Each Party shall designate a Person or Persons who shall be responsible for reviewing (or having reviewed) all Proposed Publications submitted by the other Party. No later than [\*\*\*] [\*\*\*] after receipt of any Proposed Publications (and no later than [\*\*\*] [\*\*\*] in the case of an abstract, presentation summary or [\*\*\*] [\*\*\*] in the case of a poster or conference presentation), a Reviewing Party's designated Person shall notify

100

the Publishing Party in writing whether the Reviewing Party has an objection to the Proposed Publications because the Reviewing Party reasonably believes it needs to seek patent protection. If a Reviewing Party notifies a Publishing Party that it has such an objection, the Publishing Party shall reasonably cooperate with the Reviewing Party to address such concern. The Publishing Party shall reasonably consider any other suggestions of the Reviewing Party that are provided in a timely manner, and after doing so may proceed with the Proposed Publication. With respect to any proposed abstracts, manuscripts or summaries of presentations that investigators or other Third Parties propose to publish or present, such materials shall be subject to review under this Section 9.5.2 to the extent that Alector or GSK, as the case may be, has the right to do so. Subject to the foregoing review and approval process, the Global Publication Strategy shall ensure that each Party shall have the right as required by applicable Law or such Party's policies and standard operating procedures to (a) publish protocol summaries, results summaries, protocols, clinical study reports, plain language summaries and other study documents of all Clinical Studies conducted by or on behalf of such Party with respect to any Licensed Antibodies or Licensed Products during the Term of this Agreement in any clinical trial register; (b) publish the results at scientific congresses and in peer-reviewed journals; (c) publicly disclose results from other Clinical Studies where such Party determines that the results are scientifically important or relevant for patient care; and (d) make any other public disclosures of clinical data that become required due to such Party's internal policies and procedures or applicable Laws. Any publication or disclosure made by either Party pursuant to this Section 9.5.2 shall contain appropriate acknowledgements of the contribution of the other Party or Third Party to the activities that are the subject of such publication, in accordance with generally accepted academic practice.

# ARTICLE X REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

## **10.1** Representations of Authority.

Alector and GSK each represents and warrants to the other Party that, as of the Execution Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement.

#### 10.2 Consents.

Alector and GSK each represents and warrants to the other Party that, except for any Regulatory Approvals, pricing or reimbursement approvals, manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of the Licensed Antibodies and Licensed Products, all necessary consents, approvals and authorizations of all government authorities and other persons (other than as contemplated to be obtained under Section 14.16) required to be obtained by it as of the Execution Date in connection with the execution, delivery and performance of this Agreement have been obtained by the Execution Date.

101

## 10.3 No Conflict.

Alector and GSK each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder (as contemplated as of the Execution Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws existing as of the Execution Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Execution Date. Each Party shall, and shall cause its Affiliates to, comply with all Laws applicable to the Development, Manufacture and Commercialization of the Licensed Antibodies and the Licensed Products, including applicable Drug Regulation Laws, Clinical Investigation Laws and Health Care Laws.

## 10.4 Enforceability.

Alector and GSK each represents and warrants to the other Party that, as of the Execution Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

#### 10.5 Additional Mutual Representations and Warranties.

Alector and GSK each represents and warrants to the other Party that, as of the Execution Date, such Party and its Affiliates performing Collaboration Activities has in place or will have in place prior to its conduct of its activities under the Collaboration a written agreement or binding obligation with its employees and other personnel it appoints to perform such activities hereunder sufficient to ensure that such Party has sufficient ownership or license rights to any Collaboration Intellectual Property developed or created by such Party to grant the rights to the other Party as required to be granted under this Agreement.

## 10.6 Additional Representations and Warranties of Alector.

Alector represents and warrants to GSK that, as of the Execution Date:

- **10.6.1** Exhibit 1.8 sets forth a true, complete and accurate list of all Alector Patents owned by or exclusively licensed to Alector existing as of the Execution Date. [\*\*\*] Except for the Alector Patents listed in Exhibit 1.8, Alector does not own or have an exclusive in-license to any other Patent that Covers a Licensed Antibody or Licensed Product.
- **10.6.2** There is no pending re-examination, opposition, interference, or litigation against Alector nor its Affiliates, and neither Alector nor its Affiliates have received any written notice of any pending, alleged or threatened, re-examination, opposition, interference, or litigation, or any written communication alleging that any issued Patent within the Alector Patents is invalid or

102

unenforceable anywhere in the world, provided that the foregoing is limited to Alector's Knowledge with respect to any Alector Patents that are not owned by Alector;

10.6.3 [\*\*\*]

10.6.4 [\*\*\*]

- 10.6.5 [\*\*\*] The Alector Patents (other than Patents licensed to Alector under an Existing Third Party Agreement or licensed to Alector on a non-exclusive basis) are free and clear of any liens, charges and encumbrances that would conflict with the rights granted under this Agreement (other than non-exclusive licenses granted by Alector to its Affiliates or Third Parties or applicable obligations pursuant to the Existing Third Party Agreements).
- **10.6.6** Alector is not, nor has it received any written notice that it is, in material default (or with the giving of notice or lapse of time or both, would be in material default) under any license with respect to the Alector Intellectual Property.
- **10.6.7** Except under the Existing Third Party Agreements, Alector has not assigned, licensed, sublicensed, conveyed, encumbered or granted any interest to any Third Party under any of the Alector Patents or Alector Know-How to Develop, Manufacture or Commercialize a Licensed Antibody or Licensed Product in any field in a manner that would conflict with the rights granted (or required to be granted) to GSK hereunder, and has not entered any agreement to do any of the foregoing.
- **10.6.8** Alector has taken commercially reasonable measures to protect the secrecy and confidentiality of material Alector Know-How that Alector desires to maintain as confidential [\*\*\*];

**10.6.9** [\*\*\*]

- **10.6.10** Neither Alector nor any of its Affiliates has received any warning letters or written correspondence from any Regulatory Authority or other Governmental Authority requiring the termination or suspension or material modification of any clinical studies with respect to the Existing Antibodies and Existing Products, or commencing or threatening withdrawal of any active IND held by Alector with respect to an Existing Antibody or Existing Product.
- **10.6.11** Alector has made available to GSK complete and accurate copies of all INDs submitted to the FDA by Alector or its Affiliates for the Existing Antibodies and Existing Products.

10.6.12 [\*\*\*]

<u>**10.6.13**</u> Alector holds, and in all material respects is operating in compliance with, such Regulatory Approvals and other exceptions, permits, licenses, franchises, authorizations and

103

clearances of the FDA or any other Regulatory Authority required in connection with the Development to date of the Existing Antibodies and Existing Products.

- **10.6.14** Alector has not received any written notice from any Regulatory Authority or other Governmental Authority commencing or threatening withdrawal of any active IND with respect to the Existing Antibodies and Existing Products held by Alector.
- <u>10.6.15</u> Alector is in compliance in all material respects with all Laws (including Data Privacy and Security Laws) that are applicable to its Development of the Existing Antibodies and Existing Products. Without limiting the foregoing, all of the Clinical Studies of the Existing Antibodies and Existing Products conducted prior to, or being conducted on, the Execution Date have been and on the Execution Date are being conducted in accordance with applicable Laws (including Data Privacy and Security Laws) in all material respects.
- **10.6.16** Alector has provided or made available to GSK all material adverse information with respect to the safety and efficacy of the Licensed Antibodies of which Alector is aware, including all adverse information that has been reported to the applicable Regulatory Authorities.
- **10.6.17** There are no written complaints or notices, or any pending or, to Alector's Knowledge, threatened audits, proceedings, investigations or claims conducted or asserted against Alector by any Government Authority regarding Alector's collection or use of Personally Identifiable Information by or on behalf of Alector in the conduct of Clinical Studies of the Existing Product.
- **10.6.18** Prior to beginning any development of any Licensed Antibody or Licensed Product, each employee of Alector or its Affiliates were bound by non-disclosure and invention assignment obligations.

## 10.7 Existing Third Party Agreements.

Alector represents and warrants that, prior to the Execution Date, Alector has provided GSK with an opportunity to review complete and correct copies of the Existing Third Party Agreements (including any amendments thereof), except that portions of such Existing Third Party Agreements that do not pertain to a Licensed Product or Licensed Antibody may have been redacted. Such Existing Third Party Agreements remain in full force and effect as of the Execution Date and Alector has complied in all material respects with its obligations thereunder. Such Existing Third Party Agreements are the only agreements as of the Execution Date between Alector and any Third Party that impose an obligation to pay royalties to a Third Party based on sales of the Licensed Product in the Field. Alector is not in breach under any Existing Third Party Agreements, nor, to Alector's Knowledge, is any counterparty thereto in breach of such Existing Third Party Agreement; and Alector will not during the Term, (a) knowingly commit any acts that would cause or permit termination of any Existing Third Party Agreements, or (b) amend or otherwise modify,

104

or knowingly permit to be amended or modified, any Existing Third Party Agreements in any way that would conflict with the rights granted to GSK hereunder without prior written consent of GSK.

#### 10.8 No Warranties.

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE LICENSED ANTIBODIES AND THE LICENSED PRODUCTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF THE LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE PRODUCTS WILL BE ACHIEVED.

#### 10.9 No Debarment.

- <u>10.9.1</u> Each Party represents and warrants that, as of the Execution Date, neither it nor any of its employees nor to its Knowledge, any of the agents performing hereunder, has ever been, is currently, or is the subject of a proceeding that could lead to it or such employees or agents becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual. For purposes of this provision, the following definitions shall apply:
- (a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.
- (b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.
- (c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

105

(d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

# **10.10** Compliance with Anti-Corruption Laws.

- **10.10.1** Notwithstanding anything to the contrary in the Agreement, each Party hereby agrees that:
- (a) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the U.S. Foreign Corrupt Practices Act, collectively "Anti-Corruption Laws") that is applicable to such Party; and
- (b) it has not and shall not, in connection with the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree, authorize or promise to make any payment or offer or transfer anything of value, to a Government Official, to any political party or any candidate for political office or to any other Third Party related to the transaction with the purpose of influencing decisions related to either Party and/or its business in a manner that would violate Anti-Corruption Laws. For the purpose of this Agreement, "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organization such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above. "Government Official" shall include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting either Party's business.
- **10.10.2** Either Party shall be entitled to terminate this Agreement immediately on written notice to the other Party, if such other Party fails to comply with this Section 10.10.

# 10.11 Insurance.

**10.11.1** Beginning at the time any Licensed Product is being distributed, sold or Commercialized, Alector will secure and maintain in full force and effect adequate insurance coverage against its liabilities under this Agreement including commercial general liability in an amount not less than [\*\*\*] per occurrence and annual aggregate and product liability insurance in

106

an amount not less than [\*\*\*] per occurrence and annual aggregate. Prior to the initiation of any Clinical Study by Alector, Alector shall secure and maintain in full force and effect clinical trial insurance in compliance with applicable Law in those territories where Clinical Studies are conducted. Upon written request, Alector shall provide the other with a certificate of insurance evidencing the required coverage. Notwithstanding the foregoing, Alector may self-insure, in whole or in part, the insurance requirements described above, provided that Alector is and continues to be investment grade determined by reputable and accepted financial rating agencies.

- **10.11.2** GSK shall maintain, at its cost, insurance or self-insurance with respect to liabilities and other risks associated with its activities and obligations under this Agreement, including its indemnification obligations herein, in such amounts and on such terms as are customary for prudent practices for large companies in the pharmaceutical industry for the activities to be conducted by GSK under this Agreement. GSK shall furnish to Alector evidence of such insurance or self-insurance, upon reasonable request.
- **10.11.3** Notwithstanding the foregoing, either Party's failure to maintain adequate insurance shall not relieve that Party of its obligations set forth in this Agreement.

# 10.12 Data Privacy and Security.

Each Party covenants that it will comply with all applicable Data Security and Privacy Laws in its performance of its obligations under this Agreement, in all material respects. The Parties shall enter into a written agreement governing Personally Identifiable Information prior to exchanging any Personally Identifiable Information under this Agreement including, in the case of an transfers of Personal Data outside the EEA, the Standard Contractual Clauses and/or other required measures under applicable Law to safeguard such Personal Data.

# 10.13 Post-Closing Covenants.

After the Execution Date and during the Term, Alector shall not, and shall cause its Affiliates not to, without the prior written consent of GSK:

- (a) enter into any agreement with any Third Party, whether written or oral, with respect to, or otherwise assign, transfer, license or convey its right, title or interest in or to the Alector Intellectual Property in a manner that creates a material conflict with the rights granted by Alector to GSK under this Agreement; and
- (b) (i) sell, out-license, grant a security interest over or otherwise encumber or dispose of any assets or rights relating to any Licensed Antibody or Licensed Product, in a manner that creates a material conflict with the rights granted by Alector to GSK under this Agreement or (ii) amend any agreements, licenses or other rights of Alector or any of its Affiliates, including, for clarity, any Existing Third Party Agreements in a manner that creates a material

107

conflict with the rights granted by Alector to GSK under this Agreement, without GSK's prior written consent.

# ARTICLE XI INDEMNIFICATION

# 11.1 General Indemnification By Alector.

Alector shall indemnify and hold harmless GSK, its Affiliates and their respective directors, officers, employees and agents (collectively, the "GSK Indemnified Parties"), from, against and in respect of any and all Actions, damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, Government Orders, taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts fees and expenses), resulting from a claim or Action of a Third Party or Governmental Authority (collectively, "Losses"), incurred or suffered by the GSK Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: [\*\*\*].

# 11.2 General Indemnification By GSK.

GSK shall indemnify and hold harmless Alector, its Affiliates and their respective directors, officers, employees and agents (collectively, the "**Alector Indemnified Parties**"), from, against and in respect of any and all Losses incurred or suffered by the Alector Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: [\*\*\*].

# 11.3 Product Liability Costs.

Except with respect to such portion (if any) of Product Liability Costs that are Losses entitled to indemnification under clause (ii) of Section 11.1 or clause (ii) of Section 11.2, all Product Liability Costs reasonably allocable to (a) Development of Cost Profit Sharing Products under the GDP, (b) Commercialization of a Cost Profit Sharing Product (other than for any Opt Out Products) in the United States, or (c) Manufacturing activities in support of the activities within clauses (a) or (b) (the "Shared Product Liability Costs") prior to expiration or termination of the Term shall be taken into account in determining Pre-Tax Profit or Loss as, and to the extent, provided in the Financial Exhibit.

# 11.4 Claims for General Indemnification.

**11.4.1** Notice. A person entitled to indemnification under Sections 11.1 or 11.2 (an "**Indemnified Party**") shall give prompt written notification to the person from whom indemnification is sought (the "**Indemnifying Party**") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought (each, a "**Claim**") or, if earlier, upon the assertion of any such Claim by a Third Party; provided, however, failure by an Indemnified Party to give notice of a Claim as provided in this Section 11.4.1 shall

108

not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice.

- **11.4.2** <u>Defense</u>. Within [\*\*\*] [\*\*\*] after delivery of a notice of any Claim in accordance with Section 11.4.1, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense.
- **11.4.3** <u>Cooperation</u>. The Party controlling the defense of any Claim shall keep the other Party advised of the status of such Claim and the defense thereof and shall reasonably consider recommendations made by the other Party with respect thereto. The other Party shall cooperate fully with the Party controlling such defense and its Affiliates and agents in defense of the Claim (all Out-of-Pocket Costs of such cooperation to be borne by the Party controlling such defense).
- **11.4.4** <u>Settlement</u>. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld.

# 11.5 Conduct of Product Liability Claims.

- 11.5.1 Each of the Parties shall promptly notify the other in the event that any Third Party asserts or files any product liability Claim or other Action relating to alleged defects in the Licensed Product (whether design defects, manufacturing defects or defects in sales or marketing) ("Third Party Product Liability Action") against such Party. In the event of a Third Party Product Liability Action against such a single Party, the unnamed Party shall have the right, in the unnamed Party's sole discretion, to join or otherwise participate in such legal action with legal counsel selected by the unnamed Party and reasonably acceptable to the named Party. The Party named in such Third Party Product Liability Action shall have the right to control the defense of the action, but shall notify and keep the unnamed Party apprised in writing of such action and shall consider and take into account the unnamed Party's reasonable interests and requests and suggestions regarding the defense of such action. In the event of a Third Party Product Liability Action against both Parties, the Parties shall mutually agree upon which Party shall control the response to such Third Party Product Liability Action.
- **11.5.2** The non-controlling Party of a Third Party Product Liability Action shall reasonably cooperate with the controlling Party in the preparation and formulation of a defense to such Third Party Product Liability Action, and in taking other steps reasonably necessary to respond to such Third Party Product Liability Action. The controlling Party shall have the sole

109

and exclusive right to select its counsel for the defense to such Third Party Product Liability Action. If required under applicable Law in order for the controlling Party to maintain a suit in response to such Third Party Product Liability Action, the non-controlling Party shall join as a party to the suit. The controlling Party shall assume and pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings related to such Third Party Product Liability Action, including the fees and expenses of the counsel selected by it, as well as the Out-of-Pocket Costs of the non-controlling Party associated with providing assistance requested by the controlling Party or joining the suit if requested by the controlling Party or required to maintain the suit. The non-controlling Party shall also have the right to participate and be represented in any such suit by its own counsel at its own expense. All Out-of-Pocket Costs and FTE Costs incurred in connection with any litigation or proceeding related to such Third Party Product Liability Action arising from (a) Development of Licensed Antibodies or Licensed Products under the GDP, (b) Commercialization of Licensed Products (other than for any Opt Out Products) in the U.S., or (c) Manufacturing activities in support of the foregoing clauses (a) or (b) shall be taken into account in determining Pre-Tax Profit or Loss as a Shared Product Liability Cost, and to the extent, provided in the Financial Exhibit. The controlling Party shall not settle or compromise any Third Party Product Liability Action without the consent of the other Party, which consent shall not be unreasonably withheld.

# ARTICLE XII TERM AND TERMINATION

# 12.1 Term.

Unless terminated earlier in accordance with this ARTICLE XII, this Agreement shall remain in force for the period commencing on the Execution Date (subject to Section 14.16) and ending upon the later of (a) expiration of all payment obligations under this Agreement with respect to all Licensed Products in the Territory and (b) when no Licensed Products are being Developed or Commercialized (the "**Term**"). Upon the expiration of the Royalty Term and all other payment obligations for all Licensed Products with respect to a country the licenses and rights granted to GSK herein shall become non-exclusive fully-paid, royalty-free and irrevocable.

#### 12.2 Termination For Material Breach.

**12.2.1** <u>Termination</u>. Upon any material breach of this Agreement by a Party (the "**Breaching Party**"), the other Party (the "**Non-Breaching Party**") may terminate this Agreement by providing [\*\*\*] [\*\*\*] written notice to the Breaching Party in the case of a breach of a payment obligation and [\*\*\*] [\*\*\*] written notice to the Breaching Party in the case of any other material breach, which notice shall, in each case (i) expressly reference this Section 12.2, (ii) reasonably describe the alleged breach which is the basis of such termination, and (iii) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period ("**Termination Notice**"). The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period,

110

provided that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to the Licensed Product. Notwithstanding the foregoing, if such breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan, provided that no such extension shall exceed [\*\*\*] [\*\*\*] without the consent of the Non-Breaching Party.

12.2.2 [\*\*\*] 12.2.3 [\*\*\*] 12.3 [<u>\*\*\*</u>]

# 12.4 Termination for Insolvency.

Either Party may terminate this Agreement upon the occurrence of one or more of the following:

- **12.4.1** immediately upon written notice to the other Party in the event the other Party initiates a voluntary proceeding under any applicable bankruptcy code; or
- **12.4.2** immediately upon written notice to the other Party in the event the other Party becomes the subject of an involuntary proceeding under any applicable bankruptcy code and such proceeding is not dismissed or stayed within [\*\*\*] ([\*\*\*]) [\*\*\*] of its commencement.

# 12.5 Termination by GSK Unilaterally.

GSK may, upon [\*\*\*] [\*\*\*] prior written notice to Alector, unilaterally terminate this Agreement without cause, in which event this Agreement shall remain in full force and effect until the effective date of such termination.

# 12.6 Effects of Termination.

In the event of expiration or termination of this Agreement, the provisions of this Section 12.6 shall apply.

**12.6.1** Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

111

<u>**12.6.2** Non-Exclusive Remedy</u>. Notwithstanding anything herein to the contrary, expiration or termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

**12.6.3** Survival. In the event of any expiration or termination of this Agreement, the provisions set forth in ARTICLE I, ARTICLE IX (excluding Section 9.5) and ARTICLE XI (provided however that Section 11.5 shall apply only for Third Party Product Liability Actions pertaining to activities during the Term) and Sections 2.6.1 (together with Sections 2.7, 2.8, 2.9, 13.1 and 13.3, in each case solely to the extent necessary to reconcile Development Costs, Pre-Tax Profit or Losses and royalties incurred or earned during the Term or, with respect to Pre-Tax Profit or Loss and royalties, the Agreement Wind-Down Period), 3.8, 3.10, 4.5.3 (solely with respect to the reporting and reconciliation of Development Costs incurred during the Term), 4.5.4 (to the extent necessary to reimburse Development Costs incurred during the Term), 4.7 (solely with respect to Patient Samples collected during the Term or in a co-funded On-Going Clinical Study pursuant to Section 12.6.12), 7.1, 7.3-7.4 (each with respect to Licensed Product sold by GSK or its Affiliates or Sublicensees during the Agreement Wind-Down Period), 7.5 (solely with respect to Net Sales for Licensed Products sold during the Term or during the Agreement Wind-Down Period), 7.6 (to the extent necessary to reconcile and reimburse any Development Costs incurred during the Term and reconcile and share any Pre-Tax Profit or Losses based on Allowable Expenses, Other Income or Net Sales incurred or earned during the Term or for Net Sales of Licensed Product by GSK or its Affiliates or Sublicensees during the Agreement Wind-Down Period), 7.9 (for the period set forth therein), 7.10-7.16, 8.1, 10.8, 12.6, 13.1, 13.4, 14.1, 14.3, 14.4, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.14, and 14.15 and the Financial Exhibit (to the extent necessary to reconcile and share Pre-Tax Profit or Loss based on Allowable Expenses, Other Income or Net Sales incurred or earned during the Term or for Net Sales of Licensed Product by GSK or its Affiliates or Sublicensees during the Agreement Wind-Down Period), as well as any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement shall survive to the extent required. Except as otherwise provided in this ARTICLE XII, all rights and obligations of the Parties under this Agreement, including any licenses granted hereunder, shall terminate upon expiration or termination of this Agreement for any reason.

12.6.4 Regulatory Filings and Data. GSK shall, to the extent permitted by applicable Law, assign and transfer (as soon as reasonably practicable) to Alector all Regulatory Filings and Regulatory Approvals for Licensed Products that are held or controlled by or under authority of GSK or its Affiliates or Sublicensees (unless such Sublicensees are to become Sublicensees of Alector in accordance Section 12.6.7) as of the effective date of termination, and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Filings and Regulatory Approvals to Alector. GSK shall also (as soon as reasonably practicable) transfer control of and responsibility for maintaining the global safety database for Licensed Products to Alector, and Alector shall accept

112

such transfer and responsibility. GSK shall cause each of its Sublicensees to (as soon as reasonably practicable) transfer any such Regulatory Filings and Regulatory Approvals to Alector if this Agreement terminates. If applicable Law prevents or delays the transfer of ownership of any such Regulatory Filing or Regulatory Approvals to Alector, GSK shall grant, and does hereby grant, to Alector an exclusive and irrevocable right of access and reference to such Regulatory Filing and Regulatory Approvals, and shall reasonably cooperate to make the benefits of such Regulatory Filings and Regulatory Approvals available to Alector or its designee(s), provided that GSK shall not be obliged to maintain any such Regulatory Filing or Regulatory Approval or to provide reasonable cooperation to Alector beyond the date that is [\*\*\*] [\*\*\*] following the effective date of expiration or termination of this Agreement, provided such period may be extended provided that Alector reimburses GSK's reasonable costs incurred in connection with such maintenance and cooperation during any such period. As soon as reasonably practicable after the effective date of termination (or, if reasonably requested by Alector after notice of termination), GSK shall provide or make available to Alector (in electronic form to the extent reasonably requested by Alector and available to GSK in such form) copies of: (i) all such Regulatory Filings and Regulatory Approvals; and (ii) of all Data and other Know-How in its or its Affiliate's Control pertaining to any Licensed Antibody or Licensed Product, or the manufacture or use thereof, to the extent actually used in connection with a Licensed Antibody or Licensed Product during the Term (such Know-How, the "Reverted Know-How").

# 12.6.5 Technology Licenses.

(a) GSK hereby grants, and shall cause its Affiliates to grant, to Alector, effective upon the effective date of termination, [\*\*\*].

# <u>12.6.6 [\*\*\*]</u>

12.6.7 Sublicenses. GSK's (and any of its Affiliates') sublicenses to Third Parties with respect to Licensed Products shall, at the request of Alector, be assigned to Alector to the extent possible under the terms of the applicable sublicense and to the extent that the applicable sublicense solely relates to Licensed Products, subject to such Sublicensee's prior written consent. In the event Alector does not request assignment of any such sublicense, or any of such Sublicensees does not consent to such assignment, or any such sublicenses do not solely relate to Licensed Products, then the rights of GSK's Sublicensees with respect to Licensed Products under such sublicenses shall terminate concurrently with termination of GSK's rights under this Agreement with respect to Licensed Products.

12.6.8 Marks and Domains. Effective upon the effective date of termination, GSK hereby assigns and shall cause to be assigned to Alector all worldwide rights in and to (i) any Product Trademarks and Product Related Materials specific to one or more Licensed Products that GSK or any of its Affiliates used in connection with Licensed Product(s), and (ii) all Internet domain names incorporating the applicable Product Trademark(s) or any variation or part of such Product Trademark(s) as its URL address or any part of such address. It is understood that such assignment

113

shall not include the name of GSK or any of its Affiliates, nor the corporate logo, service mark, or trademark for GSK or for any of its Affiliates as a corporate entity.

12.6.9 Return of Materials. Within [\*\*\*] ([\*\*\*]) [\*\*\*] after the end of the Agreement Wind-Down Period or, to the extent there is not an Agreement Wind-Down Period, after termination of the Agreement, each Party shall destroy, and cause its Affiliates to destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or control, and provide written certification of such destruction, or prepare such tangible items of Confidential Information for shipment to the other Party, as the other Party may direct, at the first Party's expense, provided that such Party may retain one copy of such Confidential Information of the other Party hereby agrees that, with respect to tangible items and materials that contain Confidential Information of the other Party and other information, such first Party and its Affiliates shall not use or disclose the Confidential Information of the other Party contained in such items and materials following the effective date of termination. Notwithstanding the foregoing, Alector shall be permitted to retain, use and disclose tangible items and materials containing Confidential Information of GSK or its Affiliate that are necessary or useful to practice any GSK Intellectual Property that is licensed to Alector pursuant to Section 12.6.5.

12.6.10 Post-Termination Shared Product Liability Costs. In the event a Party or any of its Affiliates incurs any Shared Product Liability Costs described in Section 11.3 after the Term and after the final reconciliation of Pre-Tax Profit or Loss under Section 7.5 in accordance with Reconciliation Procedures and the Financial Exhibit, which Shared Product Liability Costs are attributable to sales or other activities under this Agreement for a Cost Profit Sharing Product for the United States prior to expiration or termination of the Term, each Party shall be responsible for [\*\*\*] of such Shared Product Liability Costs (but only to the extent attributable to sales or other activities under this Agreement for a Cost Profit Sharing Product for the United States prior to expiration or termination of the Term). Each Party will promptly pay the other Party its share of any such Shared Product Liability Costs.

12.6.11 Transition; Manufacturing; Inventory. GSK agrees, and agrees on behalf of its Affiliates, to reasonably cooperate with Alector and its designee(s) to facilitate a smooth, orderly and prompt transition of the program and activities with respect to Licensed Antibodies and Licensed Products, including any ongoing Development, Manufacturing and Commercialization of Licensed Antibodies or Licensed Products to Alector or its designee(s). If GSK or its Affiliate Manufactured any Licensed Antibody or Licensed Product, or component of either of the foregoing or other material used for the Manufacture of Licensed Antibody or Licensed Product, at the time of termination, then GSK (or its Affiliate) shall continue to provide for manufacturing of such Licensed Antibody, Licensed Product, component and material for Alector, [\*\*\*] from the date of notice of such termination until such time as Alector is able, using Commercially Reasonable Efforts to do so, to secure an acceptable alternative commercial

114

manufacturing source from which sufficient quantities of such Licensed Antibody, Licensed Product, component and material may be procured and legally sold throughout the United States and OUS Territory, but in any event no longer than [\*\*\*] [\*\*\*] (or in the case of termination by GSK under Section 12.2 above for Alector's breach, [\*\*\*] [\*\*\*]) after the effective date of termination. If a Manufacturing Subcontractor Manufactures a Licensed Antibody or Licensed Product, or component of either of the foregoing or other material used for the Manufacture of Licensed Antibody or Licensed Product, on GSK's or its Affiliate's behalf at the time of termination, upon request of Alector GSK shall use Commercially Reasonable Efforts to transfer the applicable Manufacturing Subcontract to Alector on or promptly after the effective date of termination or Wind-Down Period, as applicable, and until such transfer shall cooperate fully to make the benefits of such Manufacturing Subcontract available to Alector or its designee(s). GSK shall as soon as reasonably practicable after the effective date of termination or Wind-Down Period, as applicable, transfer to Alector, or its designee, all applicable cell banks used for the Manufacture of Reverted Products (subject to any Third Party agreements and Alector's payments there under for any transfer or use of such cell banks), Licensed Antibodies and Licensed Products, or component of either of the foregoing and other material (including reference standards) used for the Manufacture of Licensed Antibody or Licensed Product.

To the extent the Manufacture of Licensed Antibody or Licensed Product requires the use of GSK Manufacturing Know-How, Alector shall not transfer such GSK Manufacturing Know-How to a CMO (other than an Approved CMO) without the prior written approval of GSK, such approval not to be unreasonably withheld, delayed or conditioned.

12.6.12 On-Going Clinical Study. In the event that any Clinical Study with respect to Licensed Products has been Initiated and is on-going as of the effective date of any termination of this Agreement (each, an "On-Going Clinical Study"), GSK shall continue to fund GSK's share of Development Costs (or, with respect to an On-Going Clinical Study the costs of which are not shared as Development Costs, continue to fund all costs) with respect to such On-Going Clinical Study through completion, provided that to the extent such On-Going Clinical Study is being conducted under the GDP, GSK's funding obligation for such On-Going Clinical Study would not exceed GSK's share of Development Costs for such On-Going Clinical Study budgeted in the Development Budget existing as of such termination of this Agreement. In addition, if there are any On-Going Clinical Studies being conducted by or under authority of GSK or its Affiliate at the time of notice of termination, GSK agrees, as Alector may request, to (A) promptly transition to Alector or its designee some or all of such On-Going Clinical Studies and the activities related to or supporting such trials, (B) continue to conduct such On-Going Clinical Studies for a period requested by Alector up to a maximum of [\*\*\*] [\*\*\*] [\*\*\*] after the effective date of such termination, or (C) terminate such On-Going Clinical Studies in a manner consistent with applicable Laws; provided, however, that in the event that [\*\*\*] reasonably determines that an On-Going Clinical Study being run by GSK or its Affiliate would pose an unacceptable safety risk for subjects participating in such On-Going Clinical Study, then GSK shall not be obligated to continue such Clinical Study and GSK shall provide Alector with a full explanation of the safety

115

issue concern and, if requested by Alector, reasonable documentation thereof and such additional information as may be necessary to permit Alector to fully understand and assess the safety issue raised by [\*\*\*].

12.6.13 Commercialization Wind-Down. On a country-by-country basis, GSK agrees, and agrees on behalf of its Affiliates, to reasonably cooperate with Alector and its designee(s) to facilitate a smooth, orderly and prompt transition of the Commercialization of Licensed Product already commercially launched in a country as of the effective date of termination ("Launched Products") to Alector or its designee(s). If requested by Alector, to the extent permitted by applicable Law and Regulatory Approvals, GSK and its Affiliates and Sublicensees shall continue to distribute and sell, in each case on an exclusive basis, Launched Products in such country, in accordance with the terms and conditions of this Agreement, for a period requested by Alector not to exceed [\*\*\*] [\*\*\*] from the effective date of such termination (the "Agreement Wind-Down Period"), provided that Alector may terminate such activities during the Agreement Wind-Down Period upon [\*\*\*] [\*\*\*] notice to GSK, and in any case, GSK shall not be obligated to continue promoting the Licensed Product after the effective date of such termination. If Alector requests that GSK and its Affiliates and Sublicensees distribute and sell the Launched Products in a country during the Agreement Wind-Down Period, GSK and its Affiliates and Sublicensees shall have the exclusive right to sell and distribute Licensed Product during the Agreement Wind-Down Period solely to perform such distribution and sale with respect to Launched Products in such country. For the avoidance of doubt, the Parties' obligations under Sections 3.5 and 3.6 shall terminate. Any Licensed Products sold or disposed of in a country and during the period that GSK or its Affiliates or Sublicensees are continuing to sell Licensed Products in accordance with this Section 12.6.13 during the Agreement Wind-Down Period shall be subject to the applicable payments under this Agreement. After the Agreement Wind-Down Period, GSK and its Affiliates and Sublicensees shall no longer have a right to sell Licensed Products in the applicable countries hereunder, provided that GSK, subject to the following sentence, shall have the right to sell off its remaining inventory of Licensed Product. Prior to or following expiration of the Agreement Wind-Down Period, Alector shall have the right to purchase, and GSK shall sell to the extent requested by Alector, all inventory of the Licensed Antibodies and Licensed Products, and component of either of the foregoing and other material used for the Manufacture of Licensed Antibody or Licensed Product, then owned by and in the possession of GSK or its Affiliates (or owned by GSK or its Affiliate and it the possession of a CMO) at a price equal to [\*\*\*], taking into account the portion, if any, of such Supply Costs for such inventory previously shared by Alector under this Agreement. GSK shall grant, effective on the date of such purchase, a royalty-free right and license to use any trademarks, names, and logos of GSK appearing on such inventory of the applicable Licensed Products for a period of [\*\*\*] ([\*\*\*]) [\*\*\*] solely to permit the orderly sale of such inventory, subject to Alector meeting reasonable quality control standards imposed by GSK on the use of such trademarks, names, and logos, which will be consistent with the standards used by GSK prior to such termination. To the extent that applicable Law or Regulatory Approvals prevent the foregoing, the Parties agree to

116

reasonably cooperate to establish and implement an alternative mechanisms to facilitate a smooth, orderly and prompt transition of the Commercialization of Launched Products.

# ARTICLE XIII DECISION-MAKING; DISPUTE RESOLUTION

# 13.1 Referral to Executive Officers.

If the JSC does not resolve or approve any matter properly referred to it or otherwise within the scope of its authority within [\*\*\*] ([\*\*\*]) [\*\*\*] after the JSC begins considering such matter, either Party may refer the matter to the Parties' Executive Officers for attempted resolution. If, after discussing the matter in good faith and attempting to find a mutually satisfactory resolution to the issue, the Executive Officers fail to come to unanimous agreement within [\*\*\*] ([\*\*\*]) [\*\*\*] after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to by the Parties), then, (i) with respect to disputes or decisions regarding matters described in Section 13.3.1(d)), the provisions set forth in Section 13.3 shall apply, (ii) with respect to disputes or decisions regarding matters described in Section 13.3.1(d), neither Party shall have final decision-making authority and the Parties shall continue to undertake activities consistent with the terms of this Agreement and, if applicable, the then-current applicable plan or budget and (iii) with respect to all other disputes or decisions, neither Party shall have final decision-making authority and unless and until such matter is resolved in accordance with Section 13.4, and the Parties shall continue to undertake activities consistent with the terms of this Agreement and the then-current applicable plan or budget. For the avoidance of doubt, any decision that is specified in this Agreement to be made by either Party, or by agreement of both Parties, (i.e., rather than by or through the JSC, JDC, JCC or a Working Group) shall not be subject to resolution pursuant Section 13.3 or Section 13.4, but may be referred to the Executive Officers in accordance with this Section 13.1.

# 13.2 <u>Decisions to Terminate or Suspend a Study Based on Safety Concerns.</u>

**13.2.1** Right of Sponsor. The Party sponsoring or controlling any Clinical Study of a Licensed Antibody or Licensed Product (the "Sponsor") may terminate or suspend such Clinical Study, without the approval or consent of the JDC, JSC or other Party, if (i) a Regulatory Authority or safety data review board for such Clinical Study has required such termination or suspension or (ii) if the Sponsor believes in good faith that such termination or suspension is warranted because of safety or tolerability risks to the study subjects. In either case, the Sponsor shall promptly notify the other Party (the "Non-Sponsor") of such termination or suspension, and shall use reasonable efforts to notify and consult with the Non-Sponsor prior to taking such action.

**13.2.2** <u>Right of Non-Sponsor</u>. If the Non-Sponsor of any Clinical Study of a Licensed Antibody or Licensed Product believes in good faith that termination or suspension of such Clinical Study is warranted because of safety or tolerability risks to the study subjects, then the Non-Sponsor shall so notify the Sponsor and the Parties shall discuss the Non-Sponsor's concerns

117

in good faith to determine whether to terminate, suspend, modify or continue such Clinical Study. If the Parties are unable to reach agreement with respect to whether to terminate, suspend, modify or continue such Clinical Study, the matter shall be resolved by the JSC.

# 13.3 Resolution of Certain Disputes.

- **13.3.1** <u>Application to Certain Disputes</u>. The provisions of this Section 13.3 shall apply with respect to any matter within the Joint Committees' authority that falls within the scope of Sections 13.3.1(a), 13.3.1(b), 13.3.1(c) or 13.3.1(d) below that has not been resolved within the [\*\*\*] ([\*\*\*]) [\*\*\*] period following referral to Executive Officers described in Section 13.1.
- (a) *Expert Dispute*. The following matters shall be resolved by an Expert pursuant to Section 13.3.2 (each, an "Expert Dispute"): [\*\*\*].
- (b) *Alector Final Decision*. Subject to Section 2.8.3, Alector shall be entitled to make the final decision with respect to the following matters to the extent within the authority of the JSC (except to the extent such matter is provided in Section 13.3.1(a) to be an Expert Dispute or such matter is listed in Section 13.3.1(d)): [\*\*\*].
- (c) *GSK Final Decision*. Subject to Section 2.8.3, GSK shall be entitled to make the final decision with respect to the following matters to the extent within the authority of the JSC (except to the extent such matter is provided in Section 13.3.1(a) to be an Expert Dispute or such matter is listed in Section 13.3.1(d)): [\*\*\*].
- (d) *Neither Party with Final Decision*. Notwithstanding the foregoing or anything to the contrary in this Agreement, neither Party may make the final decision with respect to the following matters (and such matters shall not be resolved pursuant to Section 13.3.2 or Section 13.4): [\*\*\*].

**13.3.2** [\*\*\*]

# 13.4 Arbitration.

**13.4.1** With the exception of those matters subject to determination as provided in Sections 2.8.2, or 13.3, any dispute, claim or controversy arising from or related in any way to this Agreement or the interpretation, application, breach, termination or validity thereof, including any claim of inducement of this Agreement by fraud or otherwise, and further including any such controversy or claim involving the parent company, subsidiaries, or affiliates under common control of any Party ("**Dispute**"), shall first be referred to the Executive Officers in accordance with Section 13.1, and if it has not been resolved within the time specified in Section 13.1, will be submitted for final, binding resolution through arbitration administered by the International Chamber of Commerce pursuant to the ICC Arbitration Rules, except where those rules conflict with these provisions, in which case these provisions control. The seat of the arbitration will be

118

New York, NY, without prejudice to the arbitrators' authority to hold any meetings or hearings in any place that is convenient to them and to the parties and in accordance with the ICC Arbitration Rules.

- **13.4.2** To the extent a Dispute does not involve claims exceeding USD [\*\*\*], then the arbitration shall be conducted by a single arbitrator. If the Parties are unable to agree on an arbitrator within [\*\*\*] ([\*\*\*]) [\*\*\*] of the filing of the Answer to the Request for Arbitration or the Answer to the Notice of Counterclaims (as may be applicable), then the arbitrator shall be appointed by the International Court of Arbitration pursuant to the ICC Arbitration Rules.
- **13.4.3** When a Dispute involves claims that exceed USD [\*\*\*], then the arbitration shall be conducted by a three-member tribunal. Each party shall be entitled to appoint a neutral and impartial co-arbitrator in accordance with the ICC Arbitration Rules. The third arbitrator, who will act as president of the arbitral tribunal, shall be appointed by agreement of the co-arbitrators, in consultation with the parties, except that if such appointment does not occur within [\*\*\*] ([\*\*\*]) [\*\*\*] of the confirmation of the co-arbitrators' appointments, then the appointment shall be made by the International Court of Arbitration pursuant to the ICC Arbitration Rules.
- 13.4.4 The Parties agree that they shall share equally the costs of the arbitration, including but not limited to the arbitrator's or tribunal's fees and costs, any administrative costs incurred during the arbitration and the fees and costs of any experts appointed by the arbitrator tribunal. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses.
- <u>13.4.5</u> Settlement negotiations, including any statements made therein, shall not be admissible during the arbitration under any circumstances. Affidavits prepared for purposes of the an arbitration hearing also shall not be admissible. As to all other matters, the arbitrator or tribunal shall have sole discretion regarding the admissibility of any evidence in accordance with the ICC Arbitration Rules.
- <u>13.4.6</u> Except as necessary for enforcement of the final award, or as required by law, the existence of the Dispute, any settlement negotiations, the arbitration proceedings, any submissions (including exhibits, testimony, proposed rulings, and briefs), and all decisions by the arbitrator or tribunal shall be deemed to be Confidential Information of both Parties. The arbitrator or tribunal shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.
  - <u>13.4.7</u> All arbitration proceedings shall be conducted in the English language.
  - **13.4.8** Each Party shall have the right to be represented by counsel in all aspects of any arbitration proceeding.

119

**13.4.9** In any event, the Parties shall endeavor in good faith to complete any arbitration under this Section 13.4 within [\*\*\*] [\*\*\*] following the initiation of such arbitration.

**13.4.10** Any award of the arbitrator or tribunal may be entered in any court of competent jurisdiction for a judicial recognition of the decision and applicable orders of enforcement, and each Party may apply to any court of competent jurisdiction for appropriate temporary injunctive relief to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, in each case pending resolution of any arbitration proceeding. Without limiting the foregoing, the Parties consent to the jurisdiction of the Federal District Court for the district in which the arbitration is seated for the enforcement of these provisions and the entry of judgment on any award rendered hereunder.

13.4.11 EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL BY JURY OF ANY ISSUE WITHIN THE SCOPE OF THE AGREEMENT TO ARBITRATE AS SET FORTH IN SECTION 13.4.1.

# ARTICLE XIV MISCELLANEOUS

#### **14.1** Assignment; Successors.

Neither Party shall assign this Agreement or any of its rights or duties hereunder without the prior written consent of the other Party; provided, however, that no such consent shall be required with respect to any such assignment, (a) to an Affiliate, (b) solely in respect of Opt Out Products or Licensed Products in the OUS Territory, to a Third Party in connection with a royalty factoring transaction or (c) to a Third Party that acquires all or substantially all of the business or assets of such Party (whether by merger, reorganization, acquisition, sale or otherwise). The assigning Party shall provide the other Party prompt written notice of any such assignment. No assignment of this Agreement shall be valid and effective unless and until the assignee agrees in writing to be bound by the terms and conditions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties. Any assignment of this Agreement not in accordance with this Section 14.1 shall be null and void.

# 14.2 Alector Change of Control.

In the event of the occurrence of an Alector Change of Control during the Term, the following provisions of this Section 14.2 shall apply.

**14.2.1** <u>Certain Terms Regarding Intellectual Property and Competing Products.</u> All Alector Intellectual Property Controlled by Alector immediately prior to such Alector Change of Control shall continue to be Alector Intellectual Property for purposes of this Agreement. Patents and Know-How that were owned or controlled by the entity acquiring Alector or the Acquirer's Affiliates prior to such Alector Change of Control (collectively, the "**Acquirer**") shall not be

120

included within the Alector Intellectual Property. Additionally: [\*\*\*].

- **14.2.2** <u>Protective Procedures</u>. The Parties shall adopt reasonable operating procedures to be established by the JSC to prevent competitively sensitive Confidential Information of one Party from being disclosed to or used by the other Party.
- **14.2.3** <u>Alector Representatives</u>. Alector's rights with respect to Alector Representatives' participation in GSK's strategic planning for and observation of implementation of Commercialization of Cost Profit Sharing Products in the OUS Territory shall terminate.

# <u>14.2.4 [\*\*\*]</u>

14.2.5 Definition. As used herein, "Alector Change of Control" means (a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving Alector as a result of which either (1) the stockholders of Alector immediately preceding such transaction hold less than [\*\*\*] of the outstanding shares, or less than [\*\*\*] of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of Alector or all or substantially all of Alector's assets, including Alector's assets related to the Licensed Antibodies and Licensed Products, either directly or through one or more subsidiaries), or (2) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "Group") holds [\*\*\*] or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of Alector or all or substantially all of Alector's assets either directly or through one or more subsidiaries); (b) the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of [\*\*\*] or more of either the outstanding voting power or the then outstanding shares of Alector, in each case on a fully diluted basis; (c) individuals who, as of the date hereof, constitute the Board of Directors of such company (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors of such company; provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such company's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such company; (d) the adoption of a plan

121

relating to the liquidation or dissolution of Alector, other than in connection with a corporate reorganization (without limitation of clause (a), above); (e) the sale or disposition to a Third Party of all or substantially all the assets of Alector (determined on a consolidated basis), including Alector's assets related to the Licensed Antibodies and Licensed Products; or (f) the sale or disposition to a Third Party of assets or businesses that constitute [\*\*\*] or more of the total revenue or assets of Alector (determined on a consolidated basis), including Alector's assets or business related to the Licensed Antibodies and Licensed Products.

# 14.3 Choice of Law.

This Agreement and any Dispute shall be governed by and interpreted under, and any court action in accordance with Section 14.9 shall apply, the laws of the State of New York excluding: (i) its conflicts of laws principles; (ii) the United Nations Conventions on Contracts for the International Sale of Goods; (iii) the 1974 Convention on the Limitation Period in the International Sale of Goods (the "1974 Convention"); and (iv) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.

#### **14.4** <u>Notices</u>.

Any notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing and shall be deemed to have been delivered upon personal delivery or (i) in the case of notices provided between Parties in the continental United States, four days after deposit in the mail or the Business Day next following deposit with a reputable overnight courier and (ii) in the case of notices provided by electronic transmission (which notice shall be followed immediately by an additional notice pursuant to clause (i) above if the notice is of a default hereunder), upon confirmation of receipt by the recipient, address to the Parties at their respective addresses as follows (or at such other addresses as may have been furnished in writing by one of the Parties to the other as provided in this Section 14.4):

If to Alector: Alector, Inc.

131 Oyster Point Blvd, Ste 600 South San Francisco, CA 94080 Attention: General Counsel

With a copy to: Wilson Sonsini Goodrich & Rosati

(which shall not 650 Page Mill Road

constitute notice) Palo Alto, California 94304

Attention: Kenneth A. Clark and Matt Wiltermuth

122

If to GSK: GlaxoSmithKline

259 E Grand Ave Fifth Floor, Suite 1

San Francisco, CA 94080

Attn: SVP & Head R&D Business Development

With a copy to: GlaxoSmithKline (which shall not 980 Great West Road

constitute notice) Brentford, Middlesex TW8 9GS

United Kingdom

Attn: VP & Head of Legal Business Development & Corporate

# 14.5 Severability.

If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use their reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement. In the event a Party seeks to avoid a provision of this Agreement by asserting that such provision is invalid or otherwise unenforceable (or, in the case of Sections 3.5 or 3.6, illegal), Alector (in the event that GSK is the asserting Party) shall have the right to [\*\*\*].

### **14.6** <u>Integration</u>.

This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral. Notwithstanding the authority granted to the JSC, JDC, JCC and any Working Groups under this Agreement, this Agreement may be amended only in writing signed by authorized representatives of each of Alector and GSK. In the event of a conflict between the GDP or the U.S. Commercialization Plan, on the one hand, and this Agreement, on the other hand, the terms of this Agreement shall govern.

# 14.7 Waiver and Non-Exclusion of Remedies.

Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. Except as expressly set forth herein, the rights

123

and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available.

#### 14.8 Independent Contractors; No Agency.

Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party, including the Alector Sales Representatives, shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. Each Party is acting on its own behalf and has obtained its own legal, tax, and investment advice regarding the execution of this Agreement and the rights and obligations arising herein. The Parties shall not maintain joint bank accounts and shall not commingle funds. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the Parties' legal relationship under this Agreement shall be that of independent contractor.

# 14.9 Submission to Jurisdiction.

Each Party (i) submits to the jurisdiction of the state and federal courts sitting in New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, and (ii) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court and (iii) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 13.4. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 14.4. Nothing in this Section 14.9, however, shall affect the right of any Party to serve legal process in any other manner permitted by Law.

### **14.10** Execution in Counterparts; Facsimile Signatures.

This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

#### **14.11** No Consequential or Punitive Damages.

**14.11.1** EXCEPT FOR (A) FRAUD OR WILLFUL MISCONDUCT, (B) A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE IX, OR SECTIONS 3.5 OR 3.6, TO THE EXTENT PERMITTED BY LAW, NEITHER PARTY HERETO NOR ANY OF

124

ITS AFFILIATES WILL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

**14.11.2** NOTHING IN THIS SECTION 14.11 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS.

# 14.12 Performance by Affiliates.

To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder, provided that such Party so notifies the other Party in writing and, further provided that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

# 14.13 Force Majeure.

If and to the extent that either Party is prevented, delayed or materially hindered by a Force Majeure Event from performing any of its obligations under this Agreement and promptly so notifies the other Party, specifying the matters constituting the Force Majeure Event, then the Party so affected shall be relieved of liability to the other for failure to perform or for delay in performing such obligations (as the case may be), but shall nevertheless use Commercially Reasonable Efforts to resume full performance thereof. The affected Party shall undertake Commercially Reasonable Efforts necessary to cure or to mitigate the effects of such Force Majeure Event.

# 14.14 Further Assurance.

Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement, in each case as requested by the other Party.

# 14.15 Construction.

The Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. References to Sections include subsections, which are part of the related Section. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article, Exhibit or Exhibit means a Section or Article of, or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (ii) references to a particular statute or regulation include all rules and regulations thereunder and any successor statute, rules or

125

regulations then in effect, in each case, including the then-current amendments thereto; (iii) words in the singular or plural form include the plural and singular form, respectively; (iv) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (v) terms "including," "include(s)," "such as," and "for example" as used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (vi) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified; (vii) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (viii) all words used in this Agreement will be construed to be of such gender or number as the circumstances require; (ix) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits), and (x) neither Party or its Affiliates shall be deemed to be acting "on behalf of" the other Party hereunder, except to the extent expressly otherwise provided.

# 14.16 HSR Filings and Closing.

After the Execution Date, both Parties shall promptly, and in no less than [\*\*\*] ([\*\*\*]) [\*\*\*], file the appropriate Notification and Report Forms for the consummation of this Agreement and the transactions contemplated hereby required under the Hart Scott Rodino Antitrust Improvements Act, as amended, and the rules and regulations promulgated thereunder ("HSR Act"). The Parties shall seek to obtain the expiration or early termination of the applicable waiting period under the HSR Act, and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the United States' Federal Trade Commission ("FTC") and Department of Justice ("DOJ") and shall comply promptly with any such inquiry or request; provided, however, neither Party shall be required to consent to the divestiture or other disposition of any of its assets or the assets of its Affiliates or to consent to any other structural or conduct remedy, and each Party and its Affiliates shall have no obligation to contest, administratively or in court, any ruling, order or other action of the FTC or DOJ or any Third Party with respect to the transactions contemplated by this Agreement. Each Party shall be responsible for paying its own costs and expenses (including legal and consultants' fees) incurred in connection with obtaining clearance of the transactions contemplated hereby from the FTC and the DOJ, and the Parties shall share the filing fees incurred in connection with the filings required pursuant to the HSR Act with GSK paying [\*\*\*] ([\*\*\*]) thereof and Alector paying [\*\*\*] ([\*\*\*]) thereof. Each of the Parties hereto will furnish to the other such necessary information and reasonable assistance as the other may request in connection with the preparation of any required filings or submissions and will cooperate in responding to any inquiry from the FTC or DOJ and to any requests for additional information at the earliest practicable date, including promptly informing the other Party of such inquiry, consulting in advance before making any presentations or submissions to the FTC or DOJ, and supplying each other with copies of all material correspondence, filings or communications between either party and either the FTC or DOJ with respect to this Agreement. Such information can be shared on an outside counsel basis or subject to other restrictions to the extent deemed necessary or advisable by counsel for the disclosing Party. To the extent practicable and as permitted by the FTC or DOJ, each Party hereto shall permit representatives of the other Party to participate in material substantive meetings (whether

126

telephone or in person) with the FTC or DOJ. Neither Party shall commit to or agree with the FTC or DOJ to withdraw its filing and refile under the HSR Act without the prior written consent of the other (such consent not to be unreasonably withheld, conditioned or delayed). Notwithstanding anything to the contrary in this Agreement, this Agreement is binding upon the Parties as of the Execution Date to the extent permitted by the HSR Act, but the provisions of ARTICLE II through ARTICLE VIII (other than Sections 3.5, 3.6, 3.7, and 8.1), ARTICLE XII and Sections 13.1, 13.2, and 13.3, shall not take effect until the Effective Date. Notwithstanding any other provisions of this Agreement to the contrary, if the HSR Clearance Date has not occurred on or before the date that is [\*\*\*] ([\*\*\*]) [\*\*\*] after the Parties make their respective HSR filings, then either Party may terminate this Agreement at any time thereafter. "HSR Clearance Date" means the date upon which the applicable waiting period under the HSR Act shall have expired or been terminated early.

[Remainder of this page intentionally blank.]

127

ALECTOR, INC.
By: /s/ Arnon Rosenthal
Title: Arnon Rosenthal
GLAXO WELLCOME UK LIMITED
By: /s/ John Sadler
Title: John Sadler
[Signature Page to Collaboration and License Agreement]
128

\*\*\* Certain information has been excluded from this agreement because it is both (i) not material and (ii) would be competitively harmful if publicly

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative as

of the Execution Date.

disclosed.

# CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Arnon Rosenthal, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Alector, 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(s) 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(s) 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: August 3, 2021 /s/ Arnon Rosenthal

Arnon Rosenthal, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

### CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Calvin Yu, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Alector, 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(s) 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(s) 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: August 3, 2021 /s/ Calvin Yu

Calvin Yu
Vice President, Finance
(Principal Financial and Accounting Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Alector, Inc. (the "Company") for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 3, 2021 /s/ Arnon Rosenthal

Arnon Rosenthal, Ph.D. Chief Executive Officer (Principal Executive Officer)

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Alector, Inc. (the "Company") for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 3, 2021 /s/ Calvin Yu

Calvin Yu

Vice President, Finance (Principal Financial and Accounting Officer)