UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37766

INTELLIA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**36-4785571**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
40 Erie Street, Suite 130, Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip code)**

857-285-6200
(Registrant's telephone number, including area code)

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

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

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

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

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

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

The number of shares outstanding of the registrant's common stock as of October 26, 2018: 43,419,303 shares.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

INTELLIA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(Amounts in thousands except share and per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 293,248	$ 340,678
Accounts receivable	2,813	10,471
Prepaid expenses and other current assets	2,768	3,681
Total current assets	298,829	354,830
Property and equipment, net	16,935	15,272
Other assets	5,469	6,133
Total Assets	$ 321,233	$ 376,235
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,754	$ 2,172
Accrued expenses	9,893	7,999
Current portion of deferred revenue	14,268	21,188
Total current liabilities	25,915	31,359
Deferred revenue, net of current portion	31,996	44,111
Other long-term liabilities	52	168
Commitments and contingencies		
Stockholders' Equity:		
Common stock, $0.0001 par value; 120,000,000 shares authorized, 43,369,323 shares and 42,384,623 shares issued and outstanding, respectively	4	4
Additional paid-in capital	445,225	421,706
Accumulated deficit	(181,959)	(121,113)
Total stockholders' equity	263,270	300,597
Total Liabilities and Stockholders' Equity	$ 321,233	$ 376,235

See notes to consolidated financial statements.

INTELLIA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(Amounts in thousands except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$ 7,408	$ 7,317	$ 22,554	$ 19,449
Operating expenses:				
Research and development	23,237	17,481	69,197	46,477
General and administrative	8,270	5,711	23,481	17,812
Total operating expenses	31,507	23,192	92,678	64,289
Operating loss	(24,099)	(15,875)	(70,124)	(44,840)
Interest income	1,397	519	3,847	1,260
Net loss	$ (22,702)	$ (15,356)	$ (66,277)	$ (43,580)
Net loss per share, basic and diluted	$ (0.53)	$ (0.44)	$ (1.55)	$ (1.25)
Weighted average shares outstanding, basic and diluted	43,161	35,189	42,684	34,945

See notes to consolidated financial statements.

INTELLIA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(Amounts in thousands)

	Nine Months Ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (66,277)	$ (43,580)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,237	2,161
(Gain) Loss on disposal of property and equipment	(16)	112
Equity-based compensation	13,464	8,726
Changes in operating assets and liabilities:		
Accounts receivable	7,658	1,961
Prepaid expenses and other current assets	913	(508)
Accounts payable	(65)	(232)
Accrued expenses	1,423	302
Deferred revenue	(13,604)	(13,298)
Other assets	664	478
Other long-term liabilities	(116)	(92)
Net cash used in operating activities	(52,719)	(43,970)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(4,766)	(7,694)
Net cash used in investing activities	(4,766)	(7,694)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from options exercised	9,457	508
Issuance of shares through employee stock purchase plan	598	356
Net cash provided by financing activities	10,055	864
Net decrease in cash and cash equivalents	(47,430)	(50,800)
Cash and cash equivalents, beginning of period	340,678	273,064
Cash and cash equivalents, end of period	$ 293,248	$ 222,264
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Purchases of property and equipment unpaid at period end	$ 922	$ 601

See notes to consolidated financial statements.

1. Overview and Basis of Presentation

Intellia Therapeutics, Inc. ("Intellia" or the "Company") is a genome editing company focused on developing proprietary, curative therapeutics utilizing a biological tool known as CRISPR/Cas9.

The consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

The unaudited consolidated financial statements include the accounts of Intellia Therapeutics, Inc. and its wholly owned, controlled subsidiary, Intellia Securities Corp. All intercompany balances and transactions have been eliminated in consolidation. The only item comprising comprehensive loss is net loss.

In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

2. Summary of Significant Accounting Policies

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which superseded existing revenue recognition guidance. The Company adopted ASU 2014-09 and its related amendments (collectively known as "ASC 606") on January 1, 2018 using the modified retrospective method. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition ("ASC 605" or "legacy GAAP"). The adoption of ASC 606 represents a change in accounting principle that will more closely align revenue recognition with the delivery of the Company's goods and services and will provide financial statement readers with enhanced disclosures.

In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps:

1) Identify the contract with the customer

A contract with a customer exists when (i) the Company enters into an enforceable contract with a customer that defines each party's rights regarding the goods or services to be transferred and identifies the related payment terms, (ii) the contract has commercial substance, and (iii) the Company determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company applies judgment in determining the customer's intent and ability to pay, which is based on a variety of factors including the customer's historical payment experience, or in the case of a new customer, published credit and financial information pertaining to the customer.

2) Identify the performance obligations in the contract

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the good or service either on its own or together with other available resources, and are distinct in the context of the contract, whereby the transfer of the good or service is separately identifiable from other promises in the contract. To the extent a contract includes multiple promised goods and services, the Company must apply judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

3) Determine the transaction price

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment, which is discussed in further detail for each of the Company's collaboration agreements in Note 5. In addition, neither of the Company's contracts as of September 30, 2018 contained a significant financing component.

4) Allocate the transaction price to performance obligations in the contract

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. However, if a series of distinct services that are substantially the same qualifies as a single performance obligation in a contract with variable consideration, the Company must determine if the variable consideration is attributable to the entire contract or to a specific part of the contract. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative standalone selling prices. The Company typically determines standalone selling prices using an adjusted market assessment approach model.

5) Recognize revenue when or as the Company satisfies a performance obligation

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer. Examples of control are using the asset to produce goods or services, enhance the value of other assets, or settle liabilities, and holding or selling the asset.

As of September 30, 2018, the Company's only revenue recognized is related to collaboration agreements with third parties. As discussed in further detail in Note 5, the Company enters into out-licensing agreements which are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: nonrefundable, upfront fees; development, regulatory, and commercial milestone payments; research and development funding payments; and royalties on the net sales of licensed products. Each of these payments results in collaboration revenues, except for revenues from royalties on the net sales of licensed products, which are classified as royalty revenues.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from consideration allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the licenses. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates the probability of reaching the milestones and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be possible. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on levels of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its collaboration agreements.

The Company receives payments from its customers based on billing schedules established in each contract. The Company's contract liabilities consist of deferred revenue. Upfront payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements.

The following table presents changes in the Company's contract liabilities during the nine months ended September 30, 2018 (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine Months Ended September 30, 2018				
Contract liabilities:				
Deferred revenue	$ 59,868	$ 3,000	$ (16,604)	$ 46,264

During the nine months ended September 30, 2018, the Company recognized the following revenues as a result of changes in the contract liability balance (in thousands):

Revenue recognized in the period from:	Nine Months Ended September 30, 2018
Amounts included in the contract liability at the beginning of the period	$ 16,604

The following tables show the impact of adoption to our consolidated statement of income and balance sheet (in thousands):

	Three Months Ended September 30, 2018 Impact of changes in accounting policies		
	As Reported	Balances without adoption of ASC 606	Effect of Change Higher/(Lower)
Collaboration revenue	$ 7,408	$ 7,103	$ 305
Operating loss	(24,099)	(24,404)	305
Net loss	$ (22,702)	$ (23,007)	$ 305
Net loss per share, basic and diluted	$ (0.53)	$ (0.53)	$ -

	Nine Months Ended September 30, 2018 Impact of changes in accounting policies		
	As Reported	Balances without adoption of ASC 606	Effect of Change Higher/(Lower)
Collaboration revenue	$ 22,554	$ 23,458	$ (904)
Operating loss	(70,124)	(69,220)	(904)
Net loss	$ (66,277)	$ (65,373)	$ (904)
Net loss per share, basic and diluted	$ (1.55)	$ (1.53)	$ (0.02)

	September 30, 2018 Impact of changes in accounting policies		
	As Reported	Balances without adoption of ASC 606	Effect of Change Higher/(Lower)
Liabilities:			
Deferred revenue - current	$ 14,268	$ 17,183	$ (2,915)
Deferred revenue - noncurrent	31,996	33,608	(1,612)
Stockholders' equity:			
Accumulated deficit	$ (181,959)	$ (186,486)	$ 4,527

Costs to obtain and fulfill a contract

The Company did not incur any expenses to obtain collaboration agreements and costs to fulfill those contracts do not generate or enhance resources of the Company. As such, no costs to obtain or fulfill a contract have been capitalized in any period.

The Company has applied the new standard to all of its contracts as of January 1, 2018.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASC 606, which superseded existing revenue recognition guidance. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 effective on January 1, 2018 using the modified retrospective method. Please see the above “Revenue Recognition” section for a discussion of the Company’s updated policies related to revenue recognition and accounting for costs to obtain and fulfill a customer contract.

Impact of Adoption

The Company adopted ASC 606 using the modified retrospective method. The cumulative effect of applying the new guidance to all contracts with customers that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit as of the adoption date. As a result of applying the modified retrospective method to adopt the new guidance, the following adjustments were made to accounts on the consolidated balance sheet as of January 1, 2018:

Consolidated Balance Sheet

	January 1, 2018 (in thousands)		
	Pre-Adoption	ASC 606 Adjustment	Post-Adoption
Current portion of deferred revenue	$ 21,188	$ (2,769)	$ 18,419
Deferred revenue, net of current portion	44,111	(2,662)	41,449
Accumulated deficit	(121,113)	5,431	(115,682)

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 establishes Topic 842 which amends ASC 840, *Leases*, by introducing a lessee model that requires balance sheet recognition of most leases. Topic 842 was subsequently amended by ASU No. 2018-01, *Land Easement Practical Expedient for Transition to Topic 842*; ASU No. 2018-10, *Codification Improvements to Topic* 842, *Leases*; and ASU No. 2018-11, *Targeted Improvements*. The Company is the lessee under certain leases that are accounted for as operating leases. The proposed changes would require that substantially all of the Company's operating leases be recognized as assets and liabilities on the Company's balance sheet. ASU 2016-02 will be effective for the Company for annual periods, and interim periods within those annual periods, beginning January 1, 2019. The Company expects to adopt this new lease standard using the transition method made available by the FASB in ASU No. 2018-11, using the effective date of January 1, 2019 as our date of initial application. Using this transition method, the Company will recognize a cumulative effect adjustment to the opening balance of retained earnings on January 1, 2019. As a result of electing this method, disclosures required under the new standard will not be provided for dates or periods before January 1, 2019. Topic 842 provides several optional practical expedients in transition. The Company expects to elect the package of practical expedients which would mean the Company would not need to reassess its existing conclusions on lease identification, classification, and initial direct costs. The Company is still evaluating the election of the use-of-hindsight practical expedient. Additionally, Topic 842 allows practical expedients for ongoing accounting treatment. The Company expects to elect the short-term lease recognition exemption for all leases that qualify. This means for those leases that qualify, the Company would not recognize right-of-use ("ROU") assets or lease liabilities. The Company also expects to elect the practical expedient which allows it not to separate lease and non-lease components for all its leases.

While the Company continues to assess the effects of adoption and cannot reasonably estimate the impact at this time, the Company does expect that this standard will have a material impact on its consolidated financial statements. The Company expects the most significant effects to be the recognition of both ROU assets and lease liabilities for our operating leases as well as significant new lease-related disclosures.

3. Fair Value Measurements

The Company classifies fair value-based measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows: Level 1, quoted market prices in active markets for identical assets or liabilities; Level 2, observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

The Company's financial instruments as of September 30, 2018 and December 31, 2017 consisted primarily of cash and cash equivalents, accounts receivable and accounts payable. As of September 30, 2018 and December 31, 2017, the Company's financial assets recognized at fair value on a recurring basis consisted of the following:

	Fair Value as of September 30, 2018			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Cash equivalents	$ 289,723	$ 289,723	$ —	$ —
Total	$ 289,723	$ 289,723	$ —	$ —

	Fair Value as of December 31, 2017			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Cash equivalents	$ 330,896	$ 330,896	$ —	$ —
Total	$ 330,896	$ 330,896	$ —	$ —

The Company estimates the fair value of its cash equivalents using quoted market prices in active markets. Other financial instruments, including accounts receivable and accounts payable, are carried at cost, which approximate fair value due to the short duration and term to maturity.

4. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2018	December 31, 2017
	(In thousands)	
Employee compensation and benefits	$ 5,119	$ 4,773
Research and development and professional expenses	4,774	3,226
Accrued expenses	$ 9,893	$ 7,999

5. Collaborations

Novartis Institutes for BioMedical Research

In December 2014, the Company entered into a strategic collaboration agreement (the "Novartis Agreement") with Novartis Institutes for Biomedical Research, Inc. ("Novartis"), primarily focused on the development of new *ex vivo* CRISPR/Cas9-edited therapies using chimeric antigen receptor T cells ("CAR-T cell"s) and hematopoietic stem cells ("HSC"s).

Agreement Structure

Under the terms of the collaboration, the Company and Novartis may research potential therapeutic, prophylactic and palliative *ex vivo* applications of the CRISPR/Cas9 technology in HSCs and CAR-T cells. The Company and Novartis agreed to conduct research of HSC targets under a research plan agreed upon by both parties. Within the HSC therapeutic space, Novartis may obtain exclusive rights to a limited number of these HSC targets, to be selected by Novartis in a series of selection windows, the last of which closes 90 days before the fifth anniversary of the effective date of the Novartis Agreement. The Company has the right to choose a limited number of HSC targets for its exclusive development and commercialization per the specified selection schedule. Following these selections by Novartis and the Company, Novartis may obtain rights to research an additional limited number of HSC targets on a non-exclusive basis. If Novartis does not exercise its selection rights within each selection window, any such rights will be deemed forfeited by Novartis. Novartis is required to use commercially reasonable efforts to research, develop and commercialize a specified number of HSC products directed to each of their selected HSC targets.

The Company also agreed to collaborate with Novartis on research activities for CAR-T cell targets pursuant to a CAR-T cell program research plan approved by the CAR-T cell subcommittee of the collaboration's joint steering committee. After completion of the activities contemplated by the CAR-T cell program research plan, Novartis will assume sole responsibility for developing any products arising from that research plan and will be responsible for additional costs and expenses of developing, manufacturing and commercializing its selected research targets. Novartis is required to use commercially reasonable efforts to research, develop or commercialize at least one CAR-T cell product directed to each of its selected CAR-T cell targets. In the last two years of the five-year collaboration term, Novartis will have the option to select a limited number of targets for research, development and commercialization of *in vivo* therapies using the Company's CRISPR/Cas9 platform, on a non-exclusive basis. Following Novartis' selection of each *in vivo* target, Novartis may offer the Company the right to participate in the research and development of such targets, in which case an *in vivo* program research plan for such target will be entered into between the Company and Novartis. Novartis is required to use commercially reasonable efforts to research, develop or commercialize at least one *in vivo* product directed to each of its selected targets. Novartis' *in vivo* target selections are subject to certain restrictions, including that the targets, or all targets within a limited number of organs: (i) have not already been reserved by the Company pursuant to our limited right to do so under the agreement; (ii) are not the subject of a collaboration or pending collaboration with a third party; and (iii) are not the subject of ongoing or planned research and development by the Company.

The Company received an upfront technology access payment from Novartis of $10.0 million in January 2015 and is entitled to additional technology access fees of $20.0 million and quarterly research payments of $1.0 million, or up to $20.0 million in the aggregate, during the five-year research term. For each product under the collaboration, subject to certain conditions, the Company may be eligible to receive (i) up to $30.3 million in development milestones, including for the filing of an investigational new drug ("IND") application and for the dosing of the first patient in each of Phase IIa, Phase IIb and Phase III clinical trials, (ii) up to $50.0 million in regulatory milestones for the product's first indication, including regulatory approvals in the U.S. and European Union ("EU"), (iii) up to $50.0 million in regulatory milestones for the product's second indication, if any, including U.S. and EU regulatory approvals, (iv) royalties on net sales in the mid-single digits, and (v) net sales milestone payments of up to $100.0 million. The Company may also be eligible to receive payments for: (i) each additional HSC target selected by Novartis beyond its initial defined allocation, (ii) each *in vivo* target that Novartis selects and (iii) any exercise by Novartis of certain license options under the Novartis Agreement. Additionally, at the inception of the arrangement, Novartis invested $9.0 million to purchase the Company's Class A-1 and Class A-2 Preferred Units under a Unit Purchase Agreement (the "Unit Purchase Agreement"). The Company considered whether the Unit Purchase Agreement would be subject to combination with the Novartis Agreement and determined that they should be combined because the terms of these arrangements are closely interrelated and were negotiated contemporaneously. The Unit Purchase Agreement and the Novartis Agreement are collectively referred to herein as the "Novartis Arrangement".

The Company assessed the Novartis Arrangement in accordance with ASC 606. The Company evaluated the promised goods and services under the Novartis Arrangement and determined that the Novartis Arrangement included two performance obligations: (1) a combined performance obligation representing a series of distinct goods and services including the licenses to research, develop and commercialize HSC products and their associated research activities and the licenses to research, develop and commercialize CAR-T cell products and their associated research activities; and (2) the preferred units.

Under the Novartis Arrangement, the Company determined that the transaction price was $59.0 million consisting of the following consideration: (1) the upfront technology access payment of $10.0 million; (2) the additional technology access fees of $20.0 million; (3) the Company's estimate of variable consideration of $20.0 million related to the quarterly research payments; and (4) the payment for the preferred units of $9.0 million. None of the clinical or regulatory milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon future regulatory progress and the licensee's efforts. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur as they were determined to relate predominantly to the licenses granted to Novartis and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and when events whose outcomes are resolved or other changes in circumstances occur.

The Company first allocated $11.6 million of the transaction price to the preferred units to record the preferred units purchased by Novartis at fair value. The Company then allocated the remaining $47.4 million of the transaction price to the remaining combined performance obligation of the licenses and associated research activities for HSC and CAR-T cell products. Revenue allocated to the combined performance obligation of the licenses and associated research activities for HSC and CAR-T cell products is being recognized on a straight-line basis over a period of five years, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation.

Collaboration Revenue

Through September 30, 2018, excluding amounts allocated to Novartis' purchase of the Company's Class A-1 and Class A-2 Preferred Units, the Company had recorded a total of $37.4 million in cash and accounts receivable under the Novartis Arrangement. Through September 30, 2018, the Company has recognized $35.7 million of collaboration revenue, including $2.4 million and $7.2 million during the three and nine months ended September 30, 2018, respectively, and $2.4 million and $6.8 million during the three and nine months ended September 30, 2017, respectively, in the consolidated statements of operations related to this agreement. As of September 30, 2018, there was approximately $11.6 million of the aggregate transaction price remaining to be recognized, which will be recognized through December 2019.

As of September 30, 2018 and December 31, 2017, the Company had accounts receivable of $1.0 million and $6.0 million, respectively, and deferred revenue of $1.6 million and $11.2 million, respectively, related to this agreement. Amounts for 2018 are reflective of accounting under ASC 606 and amounts for 2017 are reflective of accounting under ASC 605 and therefore may not be comparable.

Regeneron Pharmaceuticals, Inc.

In April 2016, the Company entered into a license and collaboration agreement (the "Regeneron Agreement") with Regeneron Pharmaceuticals, Inc. ("Regeneron"). The agreement includes a product component to research, develop and commercialize CRISPR/Cas-based therapeutic products primarily focused on genome editing in the liver as well as a technology collaboration component, pursuant to which the Company and Regeneron will engage in research and development activities aimed at discovering and developing novel technologies and improvements to CRISPR/Cas technology to enhance the Company's genome editing platform. Under this agreement, the Company also may access the Regeneron Genetics Center and proprietary mouse models to be provided by Regeneron for a limited number of the Company's liver programs.

Agreement Structure

Under the terms of the collaboration, the Company and Regeneron have agreed to a target selection process, whereby Regeneron may obtain exclusive rights for up to 10 targets to be chosen by Regeneron during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Of these 10 total targets, Regeneron may select up to five non-liver targets, while the remaining targets must be focused in the liver. At the inception of the agreement, Regeneron selected the first of its 10 targets, which is subject to a co-development and co-commercialization arrangement between the Company and Regeneron.

The Company retains the exclusive right to solely develop products for certain indications. During the target selection process, the Company has the right to choose additional liver targets for its own development using commercially reasonable efforts. Certain targets that either the Company or Regeneron select are subject to further co-development and co-commercialization arrangements at the Company's or Regeneron's option, as applicable, which either can exercise pursuant to defined conditions. In July 2018, the Company and Regeneron agreed to a form of Co-Development and Co-Promotion Agreement that will be used as the basis for each co-development/co-promotion agreement directed to a target and, simultaneously, the Company and Regeneron entered into the co-development/co-promotion agreement directed to the first collaboration target, ATTR, for which the Company will be the clinical and commercial lead. In addition, subject to certain restrictions, Regeneron will be able to replace a limited number of targets with substitute targets upon the payment of a specified replacement fee, in which case exclusive rights to the replaced target revert to the Company. Regeneron's target selections are subject to certain additional restrictions, including that non-liver targets are not the subject of ongoing or planned research and development by the Company or are not the subject of a collaboration or pending collaboration with a third party.

Research activities under the collaboration will be governed by evaluation and research and development plans that will outline the parties' responsibilities under, anticipated timelines of and budgets for, the various programs. The Company will assist Regeneron with the preliminary evaluation of liver targets, and Regeneron will be responsible for preclinical research and the conduct of clinical development, manufacturing and commercialization of products directed to each of its exclusive targets under the oversight of a joint steering committee. The Company may assist, as requested by Regeneron, with the later discovery and research of product candidates directed to any selected target. For each selected target, Regeneron is required to use commercially reasonable efforts to submit regulatory filings necessary to achieve IND acceptance for at least one product directed to each applicable target, and following IND acceptance for at least one product, to develop and commercialize such product.

In connection with this collaboration, Regeneron agreed to purchase $50.0 million of the Company's common stock in a private placement under a Stock Purchase Agreement (the "Stock Purchase Agreement") concurrent with the Company's initial public offering, and the Company received a nonrefundable upfront payment of $75.0 million. In addition, the Company is eligible to earn, on a per-licensed target basis, (i) up to $25.0 million in development milestones, including for the dosing of the first patient in each of Phase I, Phase II and Phase III clinical trials, (ii) up to $110.0 million in regulatory milestones, including for the acceptance of a regulatory filing in the U.S., and U.S. and ex-U.S. regulatory approvals, and (iii) up to $185.0 million in sales-based milestone payments. The Company is also eligible to earn royalties ranging from the high single digits to low teens, in each case, on a per-product basis, which royalties are potentially subject to various reductions and offsets and are further subject to the Company's existing low- to mid-single-digit royalty obligations under a license agreement with Caribou Biosciences, Inc. ("Caribou"). In addition, Regeneron is obligated to fund 50.0 percent of the research and development costs for the transthyretin amyloidosis program, the first target selected by Regeneron, which is subject to a co-development and co-commercialization arrangement between the Company and Regeneron.

The Company considered whether the Stock Purchase Agreement would be subject to combination with the Regeneron Agreement and determined that they should be combined because the terms of these arrangements are closely interrelated and were negotiated contemporaneously. The Stock Purchase Agreement and the Regeneron Agreement are collectively referred to herein as the "Regeneron Arrangement".

The Company assessed the Regeneron Arrangement in accordance with ASC 606. The Company evaluated the promised goods and services under the Regeneron Arrangement and determined that the Regeneron Arrangement included three performance obligations: (1) a combined performance obligation including the licenses to targets and the associated research activities and evaluation plans; (2) a combined performance obligation including the technology collaboration and associated research activities; and (3) the common stock.

Under the Regeneron Arrangement, the Company determined that the transaction price was $125.0 million, consisting of the following consideration: (1) the nonrefundable upfront payment of $75.0 million; and (2) the payment for the common stock of $50.0 million. None of the clinical or regulatory milestones were included in the transaction price, as all milestone amounts were fully constrained. As part its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future regulatory progress and the licensee's efforts. Any consideration related to sales-based milestones and royalties will be recognized when the related sales occur as they were determined to relate predominantly to the licenses granted to Regeneron and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and when events whose outcome are resolved or other changes in circumstances occur.

The Company first allocated $50.0 million of the transaction price to the common stock. The common stock was sold at its standalone selling price and the Company concluded that the total discount inherent in the arrangement is entirely attributable to the combined performance obligation including the licenses to targets and associated research activities and evaluation plans and the combined performance obligation including the technology collaboration and associated research activities. As such, the remaining $75.0 million of the transaction price was allocated to the combined performance obligation including the licenses to targets and associated research activities and evaluation plans and the combined performance obligation including the technology collaboration and associated research activities on a relative standalone selling price basis. The Company estimated the standalone selling price of each combined performance obligation by taking into consideration internal estimates of research and development personnel needed to perform the research and development services, estimates of expected cash outflows to third parties for services and supplies, selling prices of comparable transactions and typical gross profit margins. As a result of this evaluation, the Company allocated $63.8 million to the combined performance obligation including the licenses to targets and associated research activities and evaluation plans and $11.2 million to the combined performance obligation

including the technology collaboration and associated research activities. The $63.8 million allocated to the combined performance obligation including the licenses to targets and associated research activities and evaluation plans is being recognized on a straight-line basis over the six-year performance period of the arrangement, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation. The $11.2 million allocated to the combined performance obligation including the technology collaboration and associated research activities is being recognized on a straight-line basis over a period beginning with the inception of the technology collaboration in September 2016 through the end of the arrangement, which, in management's judgment, is the best measure of progress towards satisfying the performance obligation and represents the Company's best estimate of the period of the obligation.

Collaboration Revenue

Through September 30, 2018, excluding the amounts allocated to Regeneron's purchase of common stock, the Company recorded a $75.0 million upfront payment and $10.5 million for research and development services under the Regeneron Arrangement. Through September 30, 2018, the Company has recognized $40.9 million of collaboration revenue, including $5.0 million and $15.4 million during the three and nine months ended September 30, 2018, respectively, and $4.9 million and $12.6 million in the three and nine months ended September 30, 2017, respectively, in the consolidated statements of operations related to this arrangement. As of September 30, 2018, there was approximately $44.6 million of the aggregate transaction price remaining to be recognized, which will be recognized ratably through April 2022.

As of September 30, 2018 and December 31, 2017, the Company had deferred revenue of $44.6 million and $54.1 million, respectively, and accounts receivable of $1.8 million and $4.5 million, respectively, related to this arrangement.

Agreement Termination Rights

The collaboration term ends in April 2022, except that Regeneron may make a one-time payment of $25.0 million to extend the term for an additional two-year period. The agreement will continue until the date when no royalty or other payment obligations are due, unless earlier terminated in accordance with the terms of the agreement. Regeneron's royalty payment obligations expire on a country-by-country and product-by-product basis upon the later of (i) the expiration of the last valid claim of the royalty-bearing patents covering such product in such country, (ii) 12 years from the first commercial sale of such product in such country, or (iii) the expiration of regulatory exclusivity for such product. The Company may terminate the agreement on a target-by-target basis if Regeneron or any of its affiliates institutes a patent challenge against the Company's CRISPR/Cas or certain other background patent rights. The Company may also terminate the agreement on a target-by-target basis if Regeneron does not proceed with the development of a product directed to a selected target within specified periods of time. Regeneron may terminate the agreement, without cause, upon 180 days written notice to the Company, either in its entirety or on a target-by-target basis, in which event, certain rights in the terminated targets and associated intellectual property revert to the Company, as described in the agreement. Following such termination, the Company may owe Regeneron royalties, in certain circumstances, up to mid-single digits on any terminated targets that the Company subsequently commercializes on a product-by-product basis for a period of 12 years after the first commercial sale of any such products. Either party may terminate the agreement either in its entirety or with respect to the technology collaboration or one or more of the targets selected by Regeneron, in the event of the other party's uncured material breach.

6. Equity-Based Compensation

Equity-based compensation expense is classified in the consolidated statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(In thousands)			
Research and development	$ 2,591	$ 1,987	$ 7,617	$ 5,048
General and administrative	1,865	1,260	5,847	3,678
Total	$ 4,456	$ 3,247	$ 13,464	$ 8,726

Restricted Stock

The following table summarizes the Company's restricted stock activity for the nine months ended September 30, 2018:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Unvested restricted stock as of January 1, 2018	479,822	$ 0.90
Granted	86,250	22.98
Vested	(378,033)	0.79
Cancelled	(44,524)	8.48
Unvested restricted stock as of September 30, 2018	143,515	$ 12.13

As of September 30, 2018, there was $2.2 million of unrecognized equity-based compensation expense related to restricted stock that is expected to vest. These costs are expected to be recognized over a weighted average remaining vesting period of 1.5 years.

Stock Options

The weighted average grant date fair value of options, estimated as of the grant date using the Black-Scholes option pricing model, was $21.29 per option and $18.19 per option for those options granted during the three and nine months ended September 30, 2018, respectively, and $13.45 and $10.73 per option for those options granted during the three and nine months ended September 30, 2017, respectively. Key assumptions used to apply this pricing model were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Risk-free interest rate	2.8%	1.9%	2.6%	1.9%
Expected life of options	6.0 years	6.0 years	5.5-6.25 years	6.0 years
Expected volatility of underlying stock	87.7%	95.4%	88.9%	93.0%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

The following is a summary of stock option activity for the nine months ended September 30, 2018:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2018	4,705,448	$ 12.09		
Granted	1,076,731	24.43		
Exercised	(982,142)	9.63		
Forfeited and Expired	(547,529)	16.55		
Outstanding at September 30, 2018	4,252,508	$ 15.20	7.98	$ 57,432
Exercisable at September 30, 2018	1,616,167	$ 10.49	6.83	$ 29,419

As of September 30, 2018, there was $30.1 million of unrecognized compensation cost related to stock options that are expected to vest. These costs are expected to be recognized over a weighted average remaining vesting period of 2.8 years.

7. Loss Per Share

The Company calculates basic (loss) earnings per share by dividing (loss) income by the weighted average number of common shares outstanding. The Company computes diluted (loss) earnings per share after giving consideration to the dilutive effect of stock options and unvested restricted stock that are outstanding during the period, except where such securities would be anti-dilutive.

Basic and diluted loss per share was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(In thousands)			
Net loss	$ (22,702)	$ (15,356)	$ (66,277)	$ (43,580)
Weighted average shares outstanding, basic and diluted	43,161	35,189	42,684	34,945
Net loss per share, basic and diluted	$ (0.53)	$ (0.44)	$ (1.55)	$ (1.25)

The following common stock equivalents were excluded from the calculation of diluted loss per share because their inclusion would have been anti-dilutive:

	Periods Ended September 30,	
	2018	2017
	(In thousands)	
Unvested restricted stock	144	766
Stock options	4,253	4,421
Total	4,397	5,187

8. Related Party Transactions

Caribou Therapeutics

In July 2014, the Company issued Caribou Therapeutics Holdco, LLC, a wholly-owned subsidiary of Caribou, 8,110,599 Junior Preferred Units. As a result of this and related transactions, Caribou owned 9.2% of the Company's voting interests as of June 30, 2018.

The Company recognized general and administrative expense of $0.1 million and $0.7 million during the three and nine months ended September 30, 2018, respectively, and $0.1 million and $0.6 million, respectively, during the three and nine months ended September 30, 2017, related to the Company's obligation to pay 30.0 percent of Caribou's patent prosecution, filing and maintenance costs.

Novartis Institutes for BioMedical Research

In connection with its entry into the collaboration and license agreement and related equity transactions with Novartis, the Company issued Novartis 4,761,905 Class A-1 Preferred Units and 2,666,666 Class A-2 Preferred Units. In August 2015, Novartis acquired 761,905 shares of the Company's Series B Preferred Stock, and in May 2016, Novartis acquired 277,777 shares of the Company's common stock in a private placement transaction concurrent with the Company's IPO. As a result of these and subsequent transactions, Novartis collectively owned 9.9% of the Company's voting interests as of June 30, 2018.

The Company recognized collaboration revenue of $2.4 million and $7.2 million during the three and nine months ended September 30, 2018, respectively, and $2.4 million and $6.8 million in the three and nine months ended September 30, 2017, respectively, in the consolidated statements of operations related to this agreement. As of September 30, 2018 and December 31, 2017, the Company had recorded accounts receivable of $1.0 million and $6.0 million, respectively, and deferred revenue of $1.6 million and $11.2 million, respectively, related to this collaboration. Refer to Note 5, *Collaborations*, for additional information regarding this collaboration agreement.

9. Subsequent Event

On October 12, 2018, the Company filed a Registration Statement on Form S-3 (the "Shelf") with the SEC in relation to the registration of common stock, preferred stock, warrants and/or units of any combination thereof (collectively, the "Securities"). The Company also simultaneously entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC, (the "Sales Agent"), to provide for the offering, issuance and sale by the Company of up to an aggregate amount of $100.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf and subject to the limitations thereof. The Company will pay to the sales agent cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement.

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

Forward-looking Information

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- *the initiation, timing, progress and results of our research and development programs and future preclinical and clinical studies, including the anticipated timing of an investigational new drug application for transthyretin amyloidosis, our lead indication;*
- *our ability to use a modular platform capability or other strategy to efficiently discover and develop product candidates, including by applying learnings from one program to other programs;*
- *our ability to research, develop or maintain a pipeline of product candidates;*
- *our ability to manufacture or obtain material for our product candidates;*
- *our ability to advance any product candidates into, and successfully complete, clinical studies, including clinical studies necessary for regulatory approval and commercialization;*
- *our ability to advance our genome editing and therapeutic delivery capabilities;*
- *the scope of protection, including patents and license rights, we are able to establish and maintain for intellectual property rights covering our product candidates and technology;*
- *our ability to operate, including commercializing products, without infringing or breaching the proprietary or contractual rights of others;*
- *the issuance or enforcement of regulatory requirements and guidance regarding preclinical and clinical studies for genome editing products;*
- *the timing or likelihood of regulatory filings and approvals;*
- *the commercialization of our product candidates, if approved;*
- *the pricing and reimbursement of our product candidates, if approved;*
- *the implementation of our business model, strategic plans for our business, product candidates and technology;*
- *estimates of our expenses, future revenues, capital requirements and our needs for additional financing;*
- *the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;*
- *our ability to maintain and establish collaborations and intellectual property licenses and rights and the scope of such rights;*
- *our financial performance or ability to obtain additional funding;*
- *developments relating to our licensors, licensees, third-parties from which we derive rights, collaborators, competitors and our industry; and*
- *other risks and uncertainties, including those listed under the caption "Risk Factors."*

All of our forward-looking statements are as of the date of this Quarterly Report on Form 10-Q only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report on Form 10-Q or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report on Form 10-Q, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report on Form 10-Q that modify or impact any of the forward-looking statements contained in this Quarterly Report on Form 10-Q will be deemed to modify or supersede such statements in this Quarterly Report on Form 10-Q.

Management Overview

Intellia Therapeutics, Inc. ("we," "us," "our," "Intellia," or the "Company") was formed in 2014 and is a leading genome editing company focused on the development of proprietary, curative therapeutics utilizing a biological tool known as CRISPR/Cas9. We believe that the CRISPR/Cas9 technology has the potential to revolutionize treatment for genetic disease by permanently editing disease-associated genes or genetic material in the human body with a single treatment course, and via cell therapies that can replace a patient's diseased cells or by using engineered immune cells to better treat cancer and immunological diseases. We intend to leverage our leading scientific expertise, clinical development experience and intellectual property ("IP") position to unlock broad therapeutic applications of CRISPR/Cas9 genome editing and develop new therapeutic products.

Our management's discussion and analysis of our financial condition and results of operations are based upon our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared by us in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), for interim periods and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended. This discussion and analysis should be read in conjunction with these unaudited consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q as well as in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

We commenced active operations in mid-2014, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical research and studies and evaluating a clinical path for our pipeline programs. To date, we have financed our operations primarily through our collaborations with Novartis Institutes for BioMedical Research, Inc., ("Novartis"), and Regeneron Pharmaceuticals, Inc., ("Regeneron"), convertible preferred stock financings, our initial public offering and concurrent private placements of our common stock, and a follow-on public offering. All of our revenue to date has been collaboration revenue. Since our inception and through September 30, 2018, we have raised an aggregate of approximately $519.2 million to fund our operations, of which $122.7 million was through our collaboration agreements, $170.5 million was from our initial public offering and concurrent private placements, $141.0 million was from a follow-on offering and $85.0 million was from the sale of convertible preferred stock.

We are building a full-spectrum genome editing company and believe our product focus, therapeutic discovery and development strength, delivery expertise and IP portfolio make us well-positioned to translate the potential of the CRISPR/Cas9 system into clinically meaningful genome editing-based therapeutics. To maximize our opportunity to rapidly develop clinically successful products, we are applying a balanced and synergistic approach with our *in vivo* and *ex vivo* initial indications. Our approach is defined by four primary criteria: (i) the type of edit—knockout, repair or insertion; (ii) the delivery modality for and modularity of *in vivo* and *ex vivo* applications; (iii) the presence of established therapeutic endpoints; and (iv) the potential for the CRISPR/Cas9 system to provide therapeutic benefits when compared to existing therapeutic modalities. Our initial indications include *in vivo* programs focused on diseases attributable to genes expressed in the liver that have significant unmet medical needs – transthyretin amyloidosis ("ATTR"), which we are co-developing with Regeneron, alpha-1 antitrypsin deficiency ("AATD"), and inborn errors of metabolism, such as primary hyperoxaluria type 1 ("PH1"). For *ex vivo* applications, our wholly owned programs focus on next-generation, engineered cell therapy solutions that we expect will ultimately be allogeneic. Our other *ex vivo* programs partnered with Novartis use CRISPR/Cas9 to potentially create improved chimeric antigen receptor T cell ("CAR-T cell") therapy, as well as engineered hematopoietic stem cell ("HSC") product candidates.

In May 2018, we presented data from ongoing non-human primate ("NHP") studies that demonstrated liver genome editing after a single systemic administration of lipid nanoparticles ("LNP"s) containing CRISPR/Cas9 cargo and an associated 60 percent reduction of transthyretin ("TTR") protein, a level that has been associated with therapeutic effects in other treatment modalities in patients. Based on these data, we are conducting investigational new drug ("IND")-enabling activities for a therapeutic to treat ATTR. In October 2018, at the European Society of Gene and Cell Therapy ("ESGCT") meeting, we presented additional data from our NHP studies further demonstrating a high correlation between liver editing and reduction of TTR. We reported that liver editing rates of approximately 35 to 40 percent in NHPs achieved a TTR protein reduction of greater than 60 percent, which is believed to be a therapeutically meaningful reduction of TTR. We also observed durability of liver editing and reduction of circulating TTR in this species for over six months. The data also demonstrated the transient nature of Intellia's proprietary modular LNP delivery system, which was rapidly cleared from circulation, with all CRISPR/Cas9 components undetectable in blood and liver within five days of administration.

Subsequent to the studies detailed above, we have observed further substantial increases in liver editing and corresponding TTR reduction rates with the inclusion (both independently and in combination) of further modifications to our guide RNA ("gRNA"), Cas9 messenger RNA ("mRNA") and lipid chemistry. Certain improvements have demonstrated up to 78 percent (mean of 59 percent) liver editing with up to 96 percent (mean reduction of 78 percent) TTR reduction in NHPs. As a result of these observations, we are further investigating the possibility of incorporating one or more of these improvements into our ongoing IND-enabling activities, which would result in submission of the IND application for our lead indication, ATTR, in 2020 in lieu of 2019. We continue to evaluate all components of our therapeutic candidates (including gRNA, Cas9 mRNA and lipid chemistry) through single and repeat dose experiments in NHPs in order to optimize our proprietary LNP-CRISPR/Cas9 delivery system. Further, we also continue to conduct studies across multiple animal models and across multiple primary liver cells to maximize editing rates through repeat dosing and formulation optimization.

We have also demonstrated continued progression of our modular LNP delivery platform capability to knock out various liver targets of interest in mice, including *SERPINA1* for liver dysfunction associated with AATD and *HAO1* for PH1. The most common genetic form of AATD is caused by a mutation in the *SERPINA1* gene, that could manifest deleterious gain-of-function effects in the liver earlier in life as well as loss-of-function effects in the lung later in life in patients. Therefore, knocking out *SERPINA1* could form the basis of a therapeutic for AATD-associated liver dysfunction. To date, we have achieved 85 percent editing of *SERPINA1* in a mouse having the human *SERPINA1* gene leading to an approximately 95 percent reduction of the encoded alpha1-antitrypsin ("AAT") protein. In PH1, excess oxalate produced in the liver, a condition called hyperoxaluria, crystallizes and accumulates in various organs and eventually causes kidney failure. Our therapeutic approach is to knock out genes involved in the metabolic pathway for oxalate production, including the gene *HAO1*, and thereby reduce the levels of glyoxylate and in turn urinary oxalate. In a mouse model of hyperoxaluria, we achieved approximately 80 percent editing of *HAO1*, leading to an approximately 45 percent reduction in urinary oxalate after a single dose. And, we also have observed up to 90 percent reduction in the protein expressed by *HAO1* in a wild type mouse. These successful levels of editing reinforce the modular nature of our LNP delivery platform, including efficient and effective delivery to hepatocytes.

In October 2018, at ESGCT, we also reported our progress in advancing complex (insertion or repair) genome editing capabilities. In our collaboration with Regeneron, we combined our modular LNP delivery system of CRISPR/Cas9 with our proprietary modular adeno-associated viral ("AAV") insertion template to achieve supratherapeutic levels (levels higher than those required in a clinical setting) of gene expression in mice. Using *F9*, the gene encoding Factor IX ("FIX"), as a model gene, we demonstrated the first robust, efficient CRISPR-mediated targeted insertion into the liver. FIX is a blood-clotting protein that is missing or defective in hemophilia B patients. Using our proprietary bi-directional template, we detected hybrid *mAlb-hF9* transcripts in over 50 percent of hepatocyte cells following a single dose and achieved circulating human FIX protein levels of over 30,000 ng/mL. We observed that by varying either the LNP or the AAV doses, we could modulate FIX levels, while still maintaining stable and ongoing expression levels in all cases throughout 12 weeks of observation. This hybrid LNP-AAV delivery approach was then applied to our wholly owned AATD program to achieve CRISPR-mediated insertion of donor template DNA encoding the *SERPINA1* gene. The insertion resulted in blood protein levels in mice that correspond to AAT blood levels that prevent progressive loss of pulmonary capacity in humans. These data show that the hybrid LNP-AAV delivery system can achieve targeted, stable insertion of DNA by combining the advantages of transient Cas9 expression via LNP-based delivery with AAV as a template delivery approach. These data further highlight the potential to simultaneously address a broad set of genetic diseases which may require complex edits.

In October 2017, we presented data from an *in vivo* mouse study showing, after a single intracerebral injection, delivery to the brain with one of our proprietary LNP formulations as demonstrated by the expression of tdTomato protein. Additionally, we presented data from another *in vivo* mouse study showing genome editing in brain tissue following single intracerebral injections of several proprietary LNP formulations. Editing was assessed under various dosing regimens with six different proprietary LNP formulations following a single intracerebral injection targeting the striatum and cerebellum. Under these various conditions, a range of editing levels from less than 1 percent up to 28 percent were achieved in the striatal and cerebellar tissue. The injections were well tolerated and the mice did not display any behavioral changes post dosing. We continue to advance our application of CRISPR/Cas9 technology to the central nervous system, including through our collaboration with Beverly Davidson, Ph.D., of the Children's Hospital of Philadelphia, who shared promising LNP delivery of green fluorescent protein ("GFP") to the striatum of NHPs at the American Society of Gene and Cell Therapy conference in May 2018 and at ESGCT in October 2018.

In December 2017, we and our collaborator Novartis shared initial data from our research collaboration on genome-edited human HSCs. These data showed successful *ex vivo* editing of the erythroid specific enhancer region of *BCL11A*, a gene associated with ameliorating sickle cell disease, and the ability of these cells to steadily engraft in mice while maintaining their desired properties. Specifically, the data showed that greater than 80 percent target site modification in HSCs and progenitor CD34+ cells was achieved following electroporation of ribonucleoprotein ("RNP") composed of Cas9 protein and a gRNA selected for efficacy and potency. In addition, we demonstrated an approximately 40 percent reduction in *BCL11A* mRNA with a corresponding two-fold increase in γ-globin transcript and 30 to 40 percent more fetal hemoglobin-positive cells above background. Editing of CD34+ cells from patient donors resulted in similar decreases in *BCL11A* mRNA and increases in γ-globin transcript. We also showed engraftment over 16 weeks following transplantation of edited human bone marrow CD34+ cells into immune compromised mice, while maintaining editing levels in engrafted cells. We did not observe any off-target events in CD34+ cells edited with the selected gRNA, as measured by targeted next generation sequencing of sites identified through in silico prediction and based on an unbiased, genome-wide, oligo-insertion detection method.

In May 2018, we and our collaborator Ospedale San Raffaele ("OSR"), presented the first update on our joint discovery and development efforts on Wilms' Tumor 1 ("WT1")-specific transgenic T cell receptors ("TCR"s). In conjunction with this presentation, we announced that our first cell therapy target is an epitope of the tumor-overexpressed protein WT1, for the treatment of acute myeloid leukemia ("AML") and other potential hematological malignancies, as well as for solid tumors. We shared findings showing the generation, characterization and advancement of WT1-specific, transgenic T cells against multiple WT1 epitopes presented on *HLA-A*02:01* and other Class I alleles. Initial data demonstrating both recognition and killing of AML cells also was presented.

At the ESGCT meeting in October 2018, we and our collaborator OSR shared an update on our progress with the presentation of *in vitro* data showing that CRISPR/Cas9 editing in T cells could achieve over 90 percent knockout of endogenous TCRs. In addition, we showed that, after insertion of WT1-specific TCRs, the engineered T cells were fully functional and capable of specifically killing approximately 40 percent of leukemic blasts that expressed WT1 antigen and the *HLA-A*02:01* allele. We continue to develop engineered T cells for acute myeloid leukemia as part of our wholly owned *ex vivo* product pipeline based on these novel TCRs and our genome editing technology.

Collaborations

Novartis

In December 2014, we entered into a strategic collaboration agreement with Novartis, primarily focused on the development of new *ex vivo* CRISPR/Cas9-edited therapies using CAR-T cells and HSCs.

Agreement Structure

Under the terms of the collaboration, we and Novartis may research potential therapeutic, prophylactic and palliative *ex vivo* applications of our CRISPR/Cas9 technology in HSCs and CAR-T cells. We and Novartis agreed to conduct research of HSC targets under a research plan agreed upon by both parties. Within the HSC therapeutic space, Novartis may obtain exclusive rights to a limited number of these HSC targets, to be selected by Novartis in a series of selection windows. We have the right to choose a limited number of HSC targets for our exclusive development and commercialization per the specified selection schedule. Following these selections by Novartis and us, Novartis may obtain rights to research an additional limited number of HSC targets on a non-exclusive basis. Novartis is required to use commercially reasonable efforts to research, develop, and commercialize a specified number of HSC products directed to each of their selected HSC targets.

We have also agreed to collaborate with Novartis on research activities for CAR-T cell targets pursuant to the CAR-T cell program research plan approved by the CAR-T cell subcommittee of the collaboration's joint steering committee. After completion of the activities contemplated by the CAR-T cell program research plan, Novartis will assume sole responsibility for developing any products arising from that research plan and the costs and expenses of developing, manufacturing and commercializing its selected research targets. Novartis is required to use commercially reasonable efforts to research, develop or commercialize at least one CAR-T cell product directed to each of its selected CAR-T cell targets.

Starting in December 2017 and through the end of the collaboration in December 2019, Novartis has the option to select a limited number of targets for research, development and commercialization of *in vivo* therapies using our CRISPR/Cas9 platform, on a non-exclusive basis. Following Novartis' selection of each *in vivo* target, Novartis may offer us the right to participate in the research and development of such targets, in which case an *in vivo* program research plan for such target will be entered into between us and Novartis. Novartis is required to use commercially reasonable efforts to research, develop and commercialize at least one *in vivo* product directed to each of its selected *in vivo* targets. Novartis' *in vivo* target selections are subject to certain restrictions, including that the targets, or all targets within a limited number of organs: (i) have not already been reserved by us pursuant to our limited right to do so under the agreement; (ii) are not the subject of a collaboration or pending collaboration with a third party; and (iii) are not the subject of ongoing or planned research and development by us.

Under the agreement, we received an upfront technology access payment of $10.0 million and are entitled to additional technology access fees of $20.0 million and quarterly research payments of $1.0 million, or up to $20.0 million in the aggregate, during the five-year research term. In addition, for each product under the collaboration, subject to certain conditions, we may be eligible to receive (i) up to $30.3 million in development milestones, including for the filing of an IND application and for the dosing of the first patient in each of Phase IIa, Phase IIb and Phase III clinical trials, (ii) up to $50.0 million in regulatory milestones for the product's first indication, including regulatory approvals in the U.S., and the European Union ("EU"), (iii) up to $50.0 million in regulatory milestones for the product's second indication, if any, including U.S. and EU regulatory approvals, (iv) royalties on net sales in the mid-single digits, and (v) net sales milestone payments of up to $100.0 million. We may also be eligible to receive payments for: (i) each additional HSC target selected by Novartis beyond its initial defined allocation, (ii) each *in vivo* target that Novartis selects and (iii) any exercise by Novartis of certain license options under the agreement. Additionally, at the inception of the arrangement, Novartis invested $9.0 million to purchase our Class A-1 and Class A-2 Preferred Units. The difference between the cash proceeds received from Novartis for the units and the $11.6 million estimated fair value of those units at the date of issuance was determined to be $2.6 million. Accordingly, $2.6 million of the upfront technology access payment was allocated to record the preferred units purchased by Novartis at fair value.

Collaboration Revenue

Through September 30, 2018, excluding amounts allocated to Novartis' purchase of our Class A-1 and Class A-2 Preferred Units, we had recorded a total of $37.4 million in cash and accounts receivable under the Novartis agreement. Through September 30, 2018, we have recognized $35.7 million of collaboration revenue, including $2.4 million and $7.2 million during the three and nine months ended September 30, 2018, respectively, and $2.4 million and $6.8 million in the three and nine months ended September 30, 2017, respectively, in the consolidated statements of operations related to this agreement. As of September 30, 2018 and December 31, 2017, we had $0.1 million and $0.6 million of accounts receivable, respectively, and deferred revenue of $1.6 million and $11.2 million, respectively, related to this agreement.

Regeneron

In April 2016, we entered into a license and collaboration agreement with Regeneron. The agreement includes a product component to research, develop and commercialize CRISPR/Cas-based therapeutic products primarily focused on genome editing in the liver as well as a technology collaboration component, pursuant to which we and Regeneron will engage in research and development activities aimed at discovering and developing novel technologies and improvements to CRISPR/Cas-based technology to enhance our genome editing platform. Under this agreement, we may access the Regeneron Genetics Center and proprietary mouse models to be provided by Regeneron for a limited number of our liver programs.

Agreement Structure

Under the terms of our collaboration, we and Regeneron have agreed to a target selection process, whereby Regeneron may obtain exclusive rights for up to 10 targets to be chosen by Regeneron during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Of these 10 total targets, Regeneron may select up to five non-liver targets, while the remaining targets must be focused in the liver.

At the inception of the agreement, Regeneron selected the first of its 10 targets, which is subject to a co-development and co-commercialization arrangement between us and Regeneron. We retain the exclusive right to solely develop products for certain targets, including targets associated with the genetic diseases PH1 and AATD. During the target selection process, we have the right to choose additional liver targets for our own development using commercially reasonable efforts. Certain targets that either we or Regeneron select may be subject to further co-development and co-commercialization arrangements at our or Regeneron's option, as applicable, which either can exercise pursuant to defined conditions. In July 2018, we and Regeneron agreed to a form of Co-Development and Co-Promotion Agreement that will be used as the basis for each co-development/co-promotion agreement directed to a target and, simultaneously, we and Regeneron entered into the co-development/co-promotion agreement directed to the first collaboration target, ATTR, for which we will be the clinical and commercial lead. In addition, subject to certain restrictions, Regeneron will be able to replace a limited number of targets with substitute targets upon the payment of a specified replacement fee, in which case exclusive rights to the replaced target revert to us. Regeneron's target selections are subject to certain additional restrictions, including that non-liver targets are not the subject of ongoing or planned research and development by us or are not the subject of a collaboration or pending collaboration with a third party.

Research activities under the collaboration will be governed by evaluation and research and development plans that will outline the parties' responsibilities under, anticipated timelines of and budgets for, the various programs. We will assist Regeneron with the preliminary evaluation of liver targets, and Regeneron will be responsible for preclinical research and the conduct of clinical development, manufacturing and commercialization of products directed to each of its exclusive targets under the oversight of a joint steering committee. We may assist, as requested by Regeneron, with the later discovery and research of product candidates directed to any selected target. For each selected target, Regeneron is required to use commercially reasonable efforts to submit regulatory filings necessary to achieve initial IND acceptance for at least one product directed to each applicable target, and following IND acceptance for at least one product, to develop and commercialize such product.

In connection with this collaboration, Regeneron agreed to purchase $50.0 million of our common stock in a private placement concurrent with our initial public offering, and we received a nonrefundable upfront payment of $75.0 million. In addition, we are eligible to earn, on a per-licensed target basis, up to $25.0 million, $110.0 million and $185.0 million in development, regulatory and sales-based milestone payments, respectively. We are also eligible to earn royalties ranging from the high single digits to low teens, in each case, on a per-product basis, which royalties are potentially subject to various reductions and offsets and are further subject to our existing low- to mid-single-digit royalty obligations under a license agreement with Caribou Biosciences, Inc. ("Caribou"). In addition, Regeneron is obligated to fund 50.0 percent of certain research and development costs for the TTR program, the first target selected by Regeneron, which is subject to a co-development and co-commercialization arrangement between us and Regeneron.

Collaboration Revenue

Through September 30, 2018, we recorded a $75.0 million upfront payment and $10.5 million for research and development services under the Regeneron agreement. Through September 30, 2018, we have recognized $40.9 million of collaboration revenue, including $5.0 million and $15.4 million during the three and nine months ended September 30, 2018, respectively, and $4.9 million and $12.6 million during the three and nine months ended September 30, 2017, respectively, in the consolidated statements of operations related to this agreement. As of September 30, 2018 and December 31, 2017, we had deferred revenue of $44.6 million and $54.1 million, respectively, and accounts receivable of $1.8 million and $4.5 million, respectively, related to this agreement.

Results of Operations

Comparison of Three Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		
	2018	2017	Increase / (decrease)
	(In thousands)		
Collaboration revenue	$ 7,408	$ 7,317	$ 91
Operating expenses:			
Research and development	23,237	17,481	5,756
General and administrative	8,270	5,711	2,559
Total operating expenses	31,507	23,192	8,315
Operating loss	(24,099)	(15,875)	(8,224)
Interest income	1,397	519	878
Net loss	$ (22,702)	$ (15,356)	$ (7,346)

Collaboration Revenue

Our revenue consists of collaboration revenue, including amounts recognized related to upfront technology access payments for licenses, technology access fees, research funding and milestone payments earned under our collaboration and license agreements with Novartis and Regeneron.

Collaboration revenue increased to $7.4 million during the three months ended September 30, 2018, as compared to $7.3 million during the three months ended September 30, 2017. The increase in collaboration revenue during the quarter ended September 30, 2018 is primarily related to the recognition of amounts under the Regeneron collaboration. The specific Regeneron related increase is driven by increased research and development services related to our TTR program, increasing to $1.8 million during the three months ended September 30, 2018 as compared to $1.7 million during the three months ended September 30, 2017.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, which includes equity-based compensation, for full-time research and development employees, facility-related expenses, overhead expenses, lab supplies and contract research services.

Research and development expenses increased $5.8 million to $23.2 million during the three months ended September 30, 2018, as compared to $17.5 million during the three months ended September 30, 2017. This increase is primarily related to an increase in research and development expenses of $2.4 million related to laboratory supplies, research materials and services for the further advancement of our early-stage research programs; and an increase in personnel-related costs of $2.1 million, which includes equity-based compensation expense, driven by our growth in headcount.

Through 2018, we expect research and development expenses to increase as we continue to grow our research and development team and advance our research plans.

General and Administrative

General and administrative expenses consist primarily of salaries and benefits, including equity-based compensation, for our executive, finance, legal, business development and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services, including IP-related legal services, and other consulting fees and expenses.

General and administrative expenses increased $2.6 million to $8.3 million during the three months ended September 30, 2018, compared to $5.7 million during the three months ended September 30, 2017. This increase was primarily related to an increase of $1.5 million in personnel-related costs, which includes equity-based compensation expense, as we grew in headcount, as well as a $0.4 million increase in legal and other IP-related expense caused by the timing of these costs year over year.

Through 2018, we expect general and administrative expenses to increase as we continue to support the research and development team and advance our research plans.

Interest Income

Interest income increased by $0.9 million to $1.4 million during the three months ended September 30, 2018 as compared to $0.5 million during the three months ended September 30, 2017. This increase was caused by an increase in our average cash balance compared to the same period in the prior year, as well as a general increase in interest rates.

Interest income is income earned on our cash equivalents. The increase in interest income is due to the increase in interest-bearing money market accounts, commercial paper and U.S. treasury securities, as compared to the same period in the prior year.

Comparison of Nine Months Ended September 30, 2018 and 2017

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		
	2018	2017	Increase / (decrease)
	(In thousands)		
Collaboration revenue	$ 22,554	$ 19,449	$ 3,105
Operating expenses:			
Research and development	69,197	46,477	22,720
General and administrative	23,481	17,812	5,669
Total operating expenses	92,678	64,289	28,389
Operating loss	(70,124)	(44,840)	(25,284)
Interest income	3,847	1,260	2,587
Net loss	$ (66,277)	$ (43,580)	$ (22,697)

Collaboration Revenue

Our revenue consists of collaboration revenue, including amounts recognized related to upfront technology access payments for licenses, technology access fees, research funding and milestone payments earned under our collaboration and license agreements with Novartis and Regeneron.

Collaboration revenue increased approximately $3.1 million to $22.6 million during the nine months ended September 30, 2018, as compared to $19.4 million during the nine months ended September 30, 2017. The increase in collaboration revenue during the nine months ended September 30, 2018 is primarily related to the recognition of amounts under the Regeneron collaboration. The specific Regeneron related increase is driven by increased research and development services related to our TTR program, increasing to $6.0 million during the nine months ended September 30, 2018 as compared to $3.2 million during the nine months ended September 30, 2017.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits, which includes equity-based compensation, for full-time research and development employees, facility-related expenses, overhead expenses, lab supplies and contract research services.

Research and development expenses increased $22.7 million to $69.2 million during the nine months ended September 30, 2018, as compared to $46.5 million during the nine months ended September 30, 2017. This increase is primarily related to an increase in research and development expenses of $11.7 million related to laboratory supplies, research materials and services for the further advancement of our early-stage research programs; an increase in personnel-related costs of $9.4 million, which includes equity-based compensation expense, driven by our growth in headcount; and $1.1 million in depreciation on lab equipment purchased during 2017 and early 2018.

Through 2018, we expect research and development expenses to increase as we continue to grow our research and development team and advance our research plans.

General and Administrative

General and administrative expenses consist primarily of salaries and benefits, including equity-based compensation, for our executive, finance, legal, business development and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services, including IP-related legal services, and other consulting fees and expenses.

General and administrative expenses increased $5.7 million to $23.5 million during the nine months ended September 30, 2018, compared to $17.8 million during the nine months ended September 30, 2017. This increase was primarily related to an increase of $4.7 million in personnel-related costs, which includes equity-based compensation expense, as we grew in headcount.

Through 2018, we expect general and administrative expenses to increase as we continue to support the research and development team and advance our research plans.

Interest Income

Interest income increased by approximately $2.6 million to $3.8 million during the nine months ended September 30, 2018 as compared to $1.3 million during the nine months ended September 30, 2017. This increase was caused by an increase in our average cash balance compared to the same period in the prior year, as well as a general increase in interest rates.

Interest income is income earned on our cash equivalents. The increase in interest income is due to the increase in interest-bearing money market accounts, commercial paper and U.S. treasury securities, as compared to the same period in the prior year.

Liquidity and Capital Resources

Since our inception through September 30, 2018, we have raised an aggregate of $519.2 million to fund our operations, of which $122.7 million was through our collaboration agreements, $170.5 million was from our initial public offering and concurrent private placements, $141.0 million was from a follow-on public offering and $85.0 million was from the sale of convertible preferred stock. As of September 30, 2018, we had $293.2 million in cash and cash equivalents.

In addition, we are entitled to receive technology access fees and research payments under our collaboration with Novartis and are also eligible to earn a significant amount of milestone payments and royalties, in each case, on a per-product basis under our collaboration with Novartis and on a per-target basis under our collaboration with Regeneron. Our ability to earn these milestones and the timing of achieving these milestones is dependent upon the outcome of our research and development activities and is uncertain at this time. Our rights to payments under our collaboration agreements are our only committed external source of funds.

On October 12, 2018, we filed a Registration Statement on Form S-3 (the "Shelf") with the SEC in relation to the registration of common stock, preferred stock, warrants and/or units of any combination thereof (collectively, the "Securities"). We also simultaneously entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC, (the "Sales Agent"), to provide for the offering, issuance and sale by us of up to an aggregate amount of $100 million of our common stock from time to time in "at-the-market" offerings under the Shelf and subject to the limitations thereof. We shall pay to the sales agent cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses, laboratory and related supplies, legal and other regulatory expenses, patent prosecution filing and maintenance costs for our licensed IP and general overhead costs. During the next twelve months, we expect our expenses to increase compared to prior periods in connection with our ongoing activities, particularly as we continue research and development and preclinical activities.

Because our research programs are still in preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of any future product candidates or whether, or when, we may achieve profitability. Until such time as we can generate substantial product revenues, if ever, we expect to finance our ongoing cash needs through equity financings and collaboration arrangements. We are entitled to technology access fees and research payments under our collaboration with Novartis. Additionally, we are eligible to earn milestone payments and royalties, in each case, on a per-product basis under our collaboration with Novartis and on a per-target basis under our collaboration with Regeneron. Except for these sources of funding, we will not have any committed external source of liquidity. To the extent that we raise additional capital through the future sale of equity, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on our research and development plans and our expectations related to the progress of our programs, we expect that our cash and cash equivalents as of September 30, 2018, as well as technology access and research funding from Novartis and Regeneron, will enable us to fund our ongoing operating expenses and capital expenditures through mid-2020, excluding any potential milestone payments or extension fees that could be earned and distributed under the collaboration agreements with Novartis and Regeneron or any strategic use of capital not currently in the base case planning assumptions. We have based this estimate on current assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

Our ability to generate revenue and achieve profitability depends significantly on our success in many areas, including: developing our delivery technologies and our CRISPR/Cas9 technology platform; selecting appropriate product candidates to develop; completing research and preclinical and clinical development of selected product candidates; obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials; developing a sustainable and scalable manufacturing process for product candidates; launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor; obtaining market acceptance of our product candidates; addressing any competing technological and market developments; negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; maintaining good relationships with our collaborators and licensors; maintaining, protecting, and expanding our portfolio of IP rights, including patents, trade secrets, and know-how; and attracting, hiring, and retaining qualified personnel.

Cash Flows

The following is a summary of cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(In millions)	
Net cash used in operating activities	$ (52.7)	$ (44.0)
Net cash used in investing activities	(4.8)	(7.7)
Net cash provided by financing activities	10.1	0.9

Net cash used in operating activities

During the nine months ended September 30, 2018 and 2017, our operating activities used net cash of $52.7 million and $44.0 million, respectively. The use of net cash in both periods primarily resulted from our net losses and changes in our working capital accounts. The increase in net cash used in operations for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 was due primarily to higher operating expenses, driven by increased research and development activities and headcount, during the nine months ended September 30, 2018 of $92.7 million as compared to $64.3 million for the nine months September 30, 2017. These higher costs were offset in part by the receipt of cash from Novartis in both nine-month periods and receipts of cash from Regeneron of $8.6 million in the nine months ended September 30, 2018 as compared with receipts of cash of $0.1 million in the nine months ended September 30, 2017.

Net cash used in investing activities

During the nine months ended September 30, 2018 and 2017, our investing activities used net cash of $4.8 million and $7.7 million, respectively. The use of cash in both periods related to purchases of property and equipment as we grow our operations and build out our office and laboratory facilities. The decrease in the nine months ended September 30, 2018 as compared with the same period in 2017 is primarily due to purchases and build-out in early 2017 related to the move to our new corporate office in December 2016.

Net cash provided by financing activities

During the nine months ended September 30, 2018 and 2017, our net cash provided by financing activities was $10.1 million and $0.9 million, respectively. Net cash provided by financing activities during the nine months ended September 30, 2018 is made up of $9.5 million in cash received from the exercise of stock options and $0.6 million in cash received from the issuance of shares through our employee stock purchase plan. Net cash provided by financing activities during the nine months ended September 30, 2017 is made up of $0.5 million in cash received from the exercise of stock options and $0.4 million in cash received from the issuance of shares through our employee stock purchase plan.

Critical Accounting Policies

Our critical accounting policies require the most significant judgments and estimates in the preparation of our consolidated financial statements. Management has determined that our most critical accounting policies are those relating to revenue recognition and equity-based compensation. As discussed in Note 2 to our consolidated financial statements, we adopted Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09") effective January 1, 2018. There have been no other significant changes to our critical accounting policies from those which were discussed in our Annual Report on Form 10-K for the year ended December 31, 2017.

Recent Accounting Pronouncements

Please read Note 2 to our consolidated financial statements included in Part I, Item 1, "Notes to Consolidated Financial Statements," of this quarterly report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Contractual Obligations

There were no material changes to our contractual obligations during the nine months ended September 30, 2018. For a complete discussion of our contractual obligations, please refer to our *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2018, we had cash equivalents of $289.7 million consisting of interest-bearing money market accounts, commercial paper and U.S. treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of these investments, we believe that we do not have any material exposure to changes in the fair value of our investment portfolio as a result of changes in interest rates. Declines in interest rates, however, would reduce future investment income.

We do not have any foreign currency or other derivative financial instruments, and we do not believe that inflation had a material effect on our results of operations during the nine months ended September 30, 2018. Inflation generally affects us by increasing our cost of labor and clinical trial costs.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our "Chief Executive Officer") and principal financial and accounting officer (our "Chief Financial Officer"), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2018.

Changes in Internal Control over Financial Reporting

No change in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation related to intellectual property, commercial arrangements and other matters, including the matters described below. The outcome of any such legal proceedings, regardless of the merits, is inherently uncertain. In addition, litigation and related matters are costly and may divert the attention of our management and other resources that would otherwise be engaged in other activities. If we were unable to prevail in any such legal proceedings, our business, results of operations, liquidity and financial condition could be adversely affected.

Caribou Intellectual Property Arbitration

On October 17, 2018, we initiated an arbitration proceeding against Caribou asserting that Caribou is violating the terms and conditions of the license agreement entered into by the Company and Caribou in July 2014 ("Caribou License"), as well as other contractual and legal rights, by using and seeking to license to third parties two patent families relating to specific structural or chemical modifications of guide RNAs, that were purportedly invented or controlled by Caribou, in our exclusive human therapeutic field. Under the Caribou License, Caribou granted to the Company a worldwide, exclusive license to all of Caribou's intellectual property relating to CRISPR/Cas9 technology for all therapeutic, prophylactic and palliative uses and applications for any or all diseases and conditions in humans, with the sole exceptions of anti-microbial and/or anti-fungal applications. The license encompassed all CRISPR/Cas9 intellectual property developed or controlled by Caribou as of July 16, 2014 and through an intellectual property cutoff date (January 30, 2018) that was necessary or useful for us to develop, manufacture or commercialize products in our field, as well as any technology developed by Caribou under a service agreement entered into by the Company and Caribou in July 2014. Caribou has asserted that the two families of intellectual property are outside the scope of our license. In accordance with the Caribou License, we have submitted a demand for arbitration seeking a declaration that the disputed intellectual property is included within the scope of our license under the Caribou License, an award of compensatory, consequential and punitive damages based on Caribou's conduct, and an injunction prohibiting Caribou from licensing or using this intellectual property in our exclusive human therapeutics field, among other claims.

University of California/University of Vienna/Charpentier Patent Interference

As reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, on April 13, 2015, UC/Vienna/Charpentier jointly filed a request with the United States Patent and Trademarks Office (the "USPTO") asking that an interference be declared between a UC/Vienna/Charpentier patent application and certain patents issued to the Broad Institute, Massachusetts Institute of Technology, the President and Fellows of Harvard College and Rockefeller University (collectively, the "Broad Institute patent family" or the "Broad"), which claim aspects of CRISPR/Cas9 systems and methods to edit genes in eukaryotic cells, including human cells. An interference is an adversarial proceeding to determine the initial inventor of a particular invention claimed in patents and patent applications owned by different parties. An interference is conducted by the USPTO's Patent Trial and Appeal Board (the "PTAB"). On January 11, 2016, the PTAB declared an interference involving one UC/Vienna/Charpentier application, 12 Broad issued patents and a Broad patent application. In the order declaring the interference, the PTAB designated UC/Vienna/Charpentier the "Senior Party" and the Broad the "Junior Party". In March 2016, the PTAB re-declared the interference to add an additional U.S. patent application owned by the Broad. On February 15, 2017, the PTAB dismissed the proceeding finding that the parties' respective patent claims involved in the interference were distinct such that they did not meet the legal requirement to proceed with the interference. Specifically, the PTAB concluded that the Broad's claims were directed to the use of CRISPR/Cas9 only in eukaryotic cells and, thus were patently distinct from UC/Vienna/Charpentier's claims, which were directed to the use of CRISPR/Cas9 in all settings. As a result of this proceeding's dismissal, the PTAB did not make a decision regarding which party actually first invented the use of CRISPR/Cas9 systems and methods to edit genes in eukaryotic cells. In April 2017, UC/Vienna/Charpentier appealed to the U.S. Court of Appeals for the Federal Circuit seeking a review and reversal of the PTAB's decision. On September 10, 2018, the Federal Circuit affirmed the PTAB's decision to terminate the interference proceeding.

"Item 3. Legal Proceedings" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 includes additional discussion of our current legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2017 and in other documents that we file with the SEC, in evaluating the Company and our business. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to Our Business, Technology and Industry

CRISPR/Cas9 genome editing technology is not yet clinically validated for human therapeutic use. The approaches we are taking to discover and develop novel therapeutics using CRISPR/Cas9 systems are unproven and may never lead to marketable products. If we are unable to develop viable product candidates, achieve regulatory approval for any such product candidate or market and sell any product candidates, we may never achieve profitability.

We are focused on developing curative medicines utilizing the CRISPR/Cas9 genome editing technology, including *in vivo* therapies and engineered cell therapies. Although there have been significant advances in the fields of gene therapy, which typically involves introducing a copy of a gene into a patient's cell, and genome editing in recent years, *in vivo* CRISPR-based genome editing technologies are relatively new, and their therapeutic utility is largely unproven. Similarly, even though cell therapy products have been developed and received regulatory approval in key jurisdictions, such as the United States ("U.S.") and European Union ("EU"), no genome-edited engineered cell therapy has been approved, and the potential to successfully do so remains unproven.

The CRISPR/Cas9 therapies, whether *in vivo* or engineered cell therapies, that we intend to develop have not yet been clinically tested by us, and we are not aware of any clinical trials for safety or efficacy having been completed by third parties involving these CRISPR/Cas9-based therapies. The scientific evidence to support the feasibility of developing *in vivo* products or engineered cell therapies based on the CRISPR/Cas9 technology is both preliminary and limited. Successful development of products by us will require solving a number of issues, including developing or obtaining technologies to safely deliver a therapeutic agent into target cells within the human body or modify human cells while outside of the body such that the modified cells can have a therapeutic effect when delivered to the patient, optimizing the efficacy and specificity of such products, and ensuring the therapeutic selectivity, efficacy and safety of such products. There can be no assurance we will be successful in solving any or all of these issues.

We have principally concentrated our research efforts to date on bringing CRISPR/Cas9-based therapeutics to the clinic for various initial indications, and our future success is highly dependent on the successful development of CRISPR-based genome editing technologies, cellular delivery methods and therapeutic applications for these indications. These indications are the principal focus of our initial development efforts, and we may decide to alter or abandon these programs as new data become available and we gain experience in developing CRISPR/Cas9-based therapeutics. We cannot be sure that our CRISPR/Cas9 efforts and technologies will yield satisfactory products that are safe and effective, scalable or profitable in our selected indications or any other indication we pursue.

Public perception and related media coverage of potential therapy-related efficacy or safety issues, including adoption of new therapeutics or novel approaches to treatment, as well as ethical concerns related specifically to genome editing and CRISPR/Cas9, may adversely influence the willingness of subjects to participate in clinical trials, or if any therapeutic is approved, of physicians and patients to accept these novel and personalized treatments. Physicians, health care providers and third-party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training, and may choose not to administer the therapy. Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies. In addition, responses by the U.S., state or foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations, or medical standards, that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs.

Our ability to generate product revenue is dependent on the success of our application of CRISPR/Cas9 technology for human therapeutic use, which is at an early stage of development and will require significant additional discovery efforts, preclinical testing and clinical studies, as well as applicable regulatory guidance for preclinical testing and clinical studies from the Food and Drug Administration ("FDA") and other regulatory authorities, before we can seek regulatory approval and begin commercial sales of any potential product candidates.

Our ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our product candidates. Any product candidates we discover will require preclinical and clinical activities and studies, regulatory review and approval in each jurisdiction in which we intend to market the products, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of a product candidate, we must conduct extensive clinical trials to demonstrate the safety, purity and potency, as well as the efficacy, of the product candidates in humans. We cannot be certain that any of our product candidates will be successful in clinical trials and, even if successful, that we will receive regulatory approval.

Our approach to developing therapies centers on using the CRISPR/Cas9 technology to introduce or remove genetic information *in vivo* to treat various disorders, or to modify human cells *ex vivo* to create therapeutic cells that can be introduced into the human body to address the underlying disease. Because these are new therapeutic approaches, discovering, developing and commercializing our product candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities that have very limited or no experience with the clinical development of CRISPR/Cas9 therapeutics;
- seeking and obtaining regulatory approval from the FDA and other regulatory authorities in light of no formal guidance regarding potential regulatory pathways for CRISPR/Cas9-based *in vivo* therapeutics, including preclinical and clinical requirements for clearance of an Investigational New Drug ("IND") and, as appropriate thereafter, a Biologics License Application ("BLA"), or corresponding applications outside the U.S.;
- educating medical personnel, including clinical investigators, regarding the potential benefits and side effect profile of each of our product candidates;
- developing processes for the safe administration of these products, including long-term follow-up for all patients who receive treatment with any of our product candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a manufacturing process and distribution network with a cost of goods that allows for an attractive return on investment; and
- establishing sales and marketing capabilities in anticipation of, and after obtaining, any regulatory approval to gain market authorization.

Additionally, because our *in vivo* technology potentially involves genome editing across multiple cell and tissue types, we are subject to many of the challenges and risks that other genome editing therapeutics and gene therapies face, including:

- regulatory guidance regarding the requirements governing gene and engineered cell therapy products have changed and may continue to change in the future. To date, only a limited number of products that involve the *in vivo* genetic modification of patient cells have been approved globally;
- improper insertion of a gene sequence into a patient's chromosome could lead to cancer, other aberrantly functioning cells or other diseases, including death;
- transient expression of the Cas9 protein within patients' cells could lead to patients having an immunological reaction towards those cells, which could be severe or life-threatening;
- corrective expression of a missing protein in patients' cells could result in the protein being recognized as foreign, and lead to a sustained immunological reaction against the expressed protein or expressing cells, which could be severe or life-threatening; and
- regulatory agencies may require extended follow-up observation periods of patients who receive treatment using genome editing products, including for example the FDA's recommended 15-year follow-up observation period for these patients, and we will need to adopt such observation periods for our product candidates if required by the relevant regulatory agency.

Further, because our *ex vivo* product candidates involve editing human cells and then manufacturing and delivering modified cells to patients, we are subject to many of the challenges and risks that engineered cell therapies face. For example, clinical trials using engineered cell therapies may require unique products to be created for each patient and such individualistic manufacturing may be both inefficient and cost-prohibitive.

To date, only a few human clinical trials utilizing *ex vivo* CRISPR/Cas9-based therapeutics have been authorized in the U.S. and EU member states; and no company or research institution has been authorized to commence human clinical trials utilizing *in vivo* CRISPR/Cas9 therapies in the U.S. or the EU member states. Further, only a limited number of human clinical trials for *in vivo* therapies or engineered cell therapies developed using other genome-editing technologies have been authorized by the FDA in the U.S. or by the relevant regulatory agencies in the EU member states. There is no certainty that the FDA or EMA will apply to CRISPR/Cas9 product candidates the same regulatory pathway and requirements it is applying to other *ex vivo* engineered cell therapeutics; and the FDA and other regulatory authorities have not yet provided written guidance regarding preclinical or clinical studies or regulatory approval pathways specific for *ex vivo* genome editing-based therapeutics. In addition, if any product candidates encounter safety or efficacy problems, developmental delays, regulatory issues or other problems, our development plans and business could be significantly harmed. Further, competitors that are developing *ex vivo* products with similar technology may experience problems with their product candidates or programs that could in turn cause us to identify problems with our product candidates and programs that would potentially harm our business.

Further, significant uncertainty exists regarding the future scope and effect of the FDA's regulatory framework, in particular relating to the review and approval of human therapeutic products because the current U.S. administration and federal legislators have publicly declared their intention to modernize the current legal framework governing the FDA. Any such changes to the FDA requirements could impact our ability to obtain approval for our products or sell them profitably. In addition, in the EU, the decision of the United Kingdom to withdraw from the EU has required the EMA to relocate to the Netherlands, and recruit and retain new personnel to review and approve our submissions for regulatory approval in Europe. EMA's relocation could result in delays and other changes that may impact the timing and our ability to obtain approval for our products. Also, upon exiting the EU, the United Kingdom may enact legislation related to the approval and oversight of human therapeutics in that nation. Until any such legislation is enacted, we will be uncertain as to its effects on our business, including our ability to seek and obtain approval for our products in the United Kingdom.

In addition, during fiscal year 2017, non-commercial entities commenced human trials involving *in vivo* CRISPR/Cas9-based therapeutics in China. Neither these entities nor the Chinese regulatory agencies have shared publicly any information on the regulatory process for clinical trial approval including specific protocol requirements. Any specific requirement from the Chinese regulatory agencies may impact our ability to submit or obtain approval for our products in China. Further, if these human trials are unsuccessful, or if they result in significant adverse events, including deaths, there could be a significant impact to the evaluation of our product candidates globally, as well as an increase in negative public opinion.

Even if we obtain regulatory approval of any product candidates, such candidates may not gain market acceptance among physicians, patients, hospitals, third-party payors and others in the medical community.

The use of the CRISPR/Cas9 system as a framework for developing genome editing-based therapies is a recent development and may not become broadly accepted by physicians, patients, hospitals, third-party payors and others in the medical community. A variety of factors will influence whether our product candidates are accepted in the market, including, for example:

- the clinical indications for which our product candidates are approved;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the incidence and severity of any side effects, including any unintended DNA changes;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates;
- availability or existence of competitive products;
- the cost of treatment in relation to alternative treatments;

- the amount of upfront costs or training required for health care providers to administer our product candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- patients' ability to access physicians and medical centers capable of delivering any therapies that we develop;
- the willingness of patients to pay out of pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- any restrictions on the use of our product candidates together with other medications;
- interactions of our product candidates with other medicines patients are taking;
- potential adverse events for any products developed, or negative interactions with regulatory agencies, by us or others in the gene therapy and genome editing fields; and
- the effectiveness of our sales and marketing efforts and distribution support.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. In addition, adverse publicity due to the ethical and social controversies surrounding the therapeutic *in vivo* use of CRISPR/Cas9, gene edited modified cells, or other therapeutics mediums, such as viral vectors that we may use in our clinical trials may limit market acceptance of our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, third-party payors or others in the medical community, we will not be able to generate significant revenue.

Negative public opinion and increased regulatory scrutiny of CRISPR/Cas9 use, genome editing or gene therapy generally may damage public perception of the safety of any product candidates that we develop and adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates.

Gene therapy in general, and genome editing in particular, remain novel technologies, with only a limited number of gene therapy products approved to date in the U.S. and EU. Public perception may be influenced by claims that gene therapy or genome editing, including the use of CRISPR/Cas9, is unsafe or unethical, or carries an undue risk of side effects, such as improper insertion of a gene sequence into a patient's chromosome could lead to cancer, and gene therapy or genome editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. In addition, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death. Serious adverse events such as these in our clinical trials, or other clinical trials involving gene therapy or genome editing products or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidate.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors, including government agencies. In addition, because our product candidates represent new approaches to the treatment of genetic-based diseases, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our gene-modifying products. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

We intend to seek approval to market our product candidates in both the U.S. and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of pharmaceutical products, including biologics, is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Research and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to use and enhance our genome editing technology to create a pipeline of product candidates, obtain regulatory approval and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on potential product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop product candidates, our commercial opportunity, if any, will be limited.

Although we have selected an initial product candidate for clinical development for our TTR program, we are at an early stage of development and our technology and approach has not yet led, and may never lead, to any product candidate appropriate for clinical development or any approved or commercially successful products. Even if we are successful in building our pipeline of product candidates, completing clinical development, obtaining regulatory approvals and commercializing product candidates will require substantial additional funding and are prone to the risks of failure inherent in therapeutic product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, or become commercially viable.

We cannot provide any assurance that we will be able to successfully advance any product candidates that we discover through the research process. Our research programs may initially show promise, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our technology and approach may not be successful in identifying product candidates for clinical development and commercialization;
- we may not be able or willing to assemble sufficient resources to acquire or discover product candidates for clinical development and commercialization;
- animal or other non-human models for the targeted disease may not be appropriate or available to conduct preclinical testing;
- testing in preclinical models may not be predictive of human clinical testing results because species have distinct genomic sequences that may require the use of species-specific guides and reagents;
- our product candidates may not succeed in preclinical or clinical testing;
- our planned risk mitigation strategy for selecting our initial indications may fail or we may not be able to efficiently apply learnings from our initial development programs to future development programs;
- we may be unable to optimize the therapeutic efficiency, specificity, or selectivity of our future product candidates;
- our therapeutic delivery systems may fail so that even a product candidate with therapeutic activity might not demonstrate a clinically meaningful therapeutic effect;
- a product candidate may not demonstrate in patients the biological, chemical and pharmacological properties identified in laboratory and preclinical studies, or they may interact with human biological systems in unforeseen, ineffective or even harmful ways;
- a product candidate may on further study not replicate the results from earlier studies or 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;
- the therapeutic effect of a product candidate may not be permanent and may diminish over time;
- a single treatment course may not be sufficient for a cure or therapeutic benefit, and it may take several treatment courses for the product to be effective;
- a well-defined and achievable pathway to regulatory approval may never materialize for a specific product candidate;
- competitors may develop alternatives that render our product candidates obsolete, redundant or less attractive;
- product candidates we develop may be covered by third-party or other exclusive rights or may not receive desired regulatory exclusivity, and we may be unable to maintain, expand or protect our intellectual property rights;

- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- we may be unable to successfully maintain existing collaborations or licensing arrangements or enter into new ones throughout the development process as appropriate; and
- a product candidate may not be accepted as safe and effective by physicians, patients, hospitals, third-party payors and others in the medical community.

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

Because we have limited financial and managerial resources, we are initially focused on specific research programs. As a result, we may fail to capitalize on other viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, 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 retain sole development and commercialization rights. For additional information regarding the factors that will affect our ability to achieve revenue from product sales, see the risk factor entitled “We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors.”

If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price. Further, our current focus on CRISPR/Cas9 technology for developing products as opposed to multiple, more proven technologies for product development increases the risk associated with our business. If we are not successful in developing a product candidate using CRISPR/Cas9 technology, we may not be able to successfully implement an alternative product development strategy.

Results, including positive results, from our initial preclinical activities and studies are not necessarily predictive of our other ongoing and future preclinical and clinical studies, and they do not guarantee or indicate the likelihood of approval of any potential product candidate by the FDA, EMA or any other regulatory agency. If we cannot replicate the positive results from any of our preclinical or clinical activities and studies, we may be unable to successfully develop, obtain regulatory approval for and commercialize any potential product candidate.

There is a high failure rate, as well as potential substantial and unanticipated delays, for product candidates progressing through preclinical and clinical studies. Even if we are able to successfully complete our ongoing and future preclinical and clinical activities and studies for any potential product candidate, we may not be able to replicate, or may have to engage in significant efforts and resource and time investments to replicate, any positive results from these or any other studies in any of our future preclinical and clinical trials, and they do not guarantee approval of any potential product candidate by the FDA, EMA or any other necessary regulatory authorities in a timely manner or at all. Companies in the pharmaceutical and biotechnology industries have commonly suffered significant setbacks or delays in clinical studies after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made before, during and after clinical studies were underway, or observations regarding the lack of safety or efficacy made in clinical studies, which could include new or previously unreported adverse events. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in the relevant laws, regulations or regulatory policy during the period of product development.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in such studies nonetheless failed to obtain FDA, EMA or other necessary regulatory agency approval. If we fail to obtain results in our on-going, planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

The reported results of our NHP studies may ultimately differ from future results as additional data are received and fully evaluated.

The reported results of the NHP studies that we have publicly disclosed, and that are discussed herein and in documents we incorporated by reference, consist of data from our ongoing and limited studies. These data were based on an analysis of the available data from an ongoing series of studies, and therefore the reported results, findings and conclusions related to these data are subject to change following further and more comprehensive review of the data or additional and new data that we expect to receive related to, or following up on, the studies. Our reported results and related data are based on assumptions, estimations, calculations and information available to us at the time we initially report the data. Results from subsequent studies may differ from, or be inconsistent with, the reported results, or different conclusions or considerations may qualify such results, once the current data or additional data have been received and further evaluated. Even once we validate the data, there is no assurance that we will be able to reproduce such data or generate improved data results in subsequent preclinical studies. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses, or may interpret or weigh the importance of data differently, which could impact the value of our technology, the approvability or commercialization of product candidates and our business in general. If the data that we have reported related to NHP differ from actual results or we are unable to reproduce similar or improved data in subsequent preclinical studies, our ability to develop, obtain approval for, and commercialize, our products may be harmed, which could harm our business, financial condition, operating results or prospects.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

All of our lead programs are still in the discovery or preclinical stage, and their risk of failure is high. It is impossible to predict when or if any of our programs will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of any of our future product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Successful completion of clinical trials is a prerequisite to submitting an BLA to the FDA, a Marketing Authorization Application to the EMA and similar filings to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We do not know whether any of our clinical trials will begin or be completed on schedule, if at all.

We may experience delays in completing our preclinical studies and initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct, which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators, institutional review boards (“IRB”s) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (“CRO”s), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be lower than required by the regulatory agencies or slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of preclinical studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other gene therapies or genome editing-based therapies that raise safety or efficacy concerns about our product candidates; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate or rely on a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board ("DSMB") for such trial or FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by FDA or other regulatory authorities resulting in the imposition of a clinical hold, manufacturing or quality control issues, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

Inconclusive results, lack of efficacy, adverse events or additional safety concerns in clinical trials that we or others conduct may impede the regulatory approval process or overall market acceptance of our future product candidates.

Therapeutic applications of genome editing technologies, and CRISPR/Cas9 in particular, for both *in vivo* products and in engineered cell therapies, are unproven and must undergo rigorous clinical trials and regulatory review before receiving marketing authorization. If the results of our clinical studies or those of any other third parties, including with respect to genome editing technology or engineered cell therapies, are inconclusive, fail to show efficacy or if such clinical trials give rise to safety concerns or adverse events, we may:

- be delayed in obtaining marketing approval for our future product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to the addition of labeling statements, such as warnings or contraindications, or other types of regulatory restrictions or scrutiny;
- be subject to changes in the way the product is administered;

- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities modify or withdraw their legal requirements or written guidance, if any, regarding the applicable regulatory approval pathway or any approval of the product in question, or impose restrictions on its distribution in the form of a modified REMS;
- be sued; or
- experience damage to our reputation.

Additionally, our future product candidates could potentially cause other adverse events that have not yet been predicted and the potentially permanent nature of genome editing effects, including CRISPR/Cas9's effects, on genes or novel cell therapies in the organs of the human body may make these adverse events irreversible. The inclusion of critically ill patients in our clinical studies or those of our competitors may result in deaths or other adverse medical events, including those due to other therapies or medications that such patients may be using. Any of these events could prevent us from achieving or maintaining regulatory approval or market acceptance of our future product candidates and impair our ability to achieve profitability.

We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate that we discover. Our ability to generate revenue and achieve and retain profitability depends significantly on our success in many areas, including:

- selecting commercially viable product candidates and effective delivery methods;
- completing research, preclinical and clinical development of product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for product candidates, including establishing and maintaining commercially viable supply relationships with third parties and potentially establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- accurately assessing the size and addressability of potential patient populations;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter or which may be necessary for us to develop, manufacture or commercialize our product candidates;
- maintaining good relationships with our collaborators and licensors;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- avoiding infringement of or obtaining licenses to any valid intellectual property owned or controlled by third parties; and
- attracting, hiring and retaining qualified personnel.

Even if one or more product candidates that we discover and develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and the timing of such costs may be out of our control. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical or other types of additional studies. If we are successful in obtaining regulatory approvals to market one or more product candidates, our

revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We face significant competition in an environment of rapid technological change. The possibility that our competitors may achieve regulatory approval before we do or develop therapies that are more advanced or effective than ours may harm our business and financial condition or our ability to successfully market or commercialize our product candidates.

The biotechnology and pharmaceutical industries, including the genome editing field and engineered cell therapies, are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

Competitors in our efforts to provide genetic therapies to patients can be grouped into at least three sets based on their product discovery platforms:

- genome editing companies focused on CRISPR/Cas9 including: Beam Therapeutics Inc., Caribou Biosciences, Inc., Casebia Therapeutics, LLC, CRISPR Therapeutics, Inc., Editas Medicine, Inc., ToolGen, Inc., and Tracr Hematology Limited;
- other genome editing companies including: bluebird bio, Inc., Cellectis S.A., Homology Medicines, Inc., Poseida, Inc., Precision BioSciences, Inc. and Sangamo Therapeutics, Inc.; and
- gene therapy companies developing *in vivo* or *ex vivo* therapies, such as cell therapies, including: bluebird bio, Inc., Cellectis S.A., Celgene Corporation (which acquired Juno Therapeutics, Inc.), Gilead Sciences, Inc. (which acquired Kite Pharma, Inc.), Novartis A.G., Spark Therapeutics, Inc., and Voyager Therapeutics, Inc.

Our competitors will also include companies that are or will be developing other genome editing methods as well as small molecules, biologics, *in vivo* gene therapies, engineered cell therapies (both autologous and allogeneic) and nucleic acid-based therapies for the same indications that we are targeting with our CRISPR/Cas9-based therapeutics.

Any advances in gene therapy, engineered cell therapies or genome editing technology made by a competitor may be used to develop therapies that could compete against any of our product candidates. Many of these competitors have substantially greater research and development capabilities and financial, scientific, technical, intellectual property, manufacturing, marketing, distribution and other resources than we do, and we may not be able to successfully compete with them.

To become and remain profitable, we must discover, develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and clinical trials of product candidates, obtaining marketing approval for product candidates, manufacturing, marketing and selling products that are approved and satisfying any post-marketing requirements. Even if we are successful in selecting and developing any product candidates, in order to compete successfully we may need to be first-to-market or demonstrate that our CRISPR/Cas9-based products are superior to therapies based on the same or different treatment methods. If we are not first-to-market or are unable to demonstrate such superiority, any products for which we are able to obtain approval may not be commercially successful. Furthermore, in certain jurisdictions, if a competitor has orphan drug status for a product and if our product candidate is determined to be contained within the scope of a competitor's orphan drug exclusivity, then approval of our product for that indication or disease could potentially be blocked, for example, for up to seven years in the U.S. and 10 years in the EU.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We have a very limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are early in our development efforts and all of our lead programs are either in the discovery or preclinical stage. We were formed in May 2014, have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

Each of our programs may require additional discovery research and then preclinical and clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. In addition, our product candidates must be approved for marketing by the FDA or certain other foreign regulatory agencies, including the EMA, before we may commercialize any product.

Our limited operating history, particularly in light of the rapidly evolving genome editing field, may make it difficult to evaluate our current business and predict our future performance. Our relatively short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred net losses in each period since our inception, anticipate that we will continue to incur net losses in the future and may never achieve profitability.

We are not profitable and have incurred losses in each period since our inception. Our net loss was $66.3 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of $182.0 million. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our future product candidates, scale-up manufacturing capabilities, maintain, expand and protect our intellectual property portfolio and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

A critical aspect of our strategy is to invest significantly in our technology to improve the efficacy and safety of potential product candidates that we discover. Even if we succeed in discovering, developing and ultimately commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

We may need to raise substantial additional funding to fund our operations. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of any product candidates.

Our operations have required substantial amounts of cash since inception, and we expect to spend substantial amounts of our financial resources on our discovery programs going forward and future development efforts. If we are able to identify product candidates that are eventually approved, we will require significant additional amounts in order to launch and commercialize our product candidates. For the foreseeable future, we expect to continue to rely on additional financing to achieve our business objectives.

We will require additional capital for the further development and commercialization of any product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate or due to other unanticipated factors.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our collaboration and license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements. We could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders and restrict our operations.

We will need additional capital in the future to continue our planned operations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity 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 experience delays or difficulties in the enrollment of patients in clinical trials, our ability to complete clinical trials or our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for any future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. If patients are unwilling to participate in our clinical studies because of concerns about, or negative publicity from, adverse events in the genome editing, gene therapy or engineered cell therapy fields, the novel nature of the CRISPR/Cas9 genome editing technology, the irreversibility of the effects of CRISPR/Cas9 or for other reasons, including competitive clinical studies for similar patient populations, then the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether. In addition, any patients who would otherwise be eligible for clinical trials that we may hold may instead enroll in clinical trials of product candidates of our competitors.

Patient enrollment is affected by other factors including:

- the size, location and nature of the patient population;
- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the design of the clinical trial;
- the availability of alternative treatments;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in clinical trials may result in increased development costs for any of our potential future product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and, while we expect to enter into agreements governing their committed activities, we will have limited influence over their actual performance.

We expect to expand our research, development and regulatory capabilities, and, as a result, we may encounter difficulties in hiring capable personnel and otherwise managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations, including the areas of technology research, product development and manufacturing, clinical, regulatory and quality affairs and, if any product candidates are submitted for or receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to recruit and train additional qualified personnel or to otherwise effectively manage the expansion of our operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business and development plans or disrupt our operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical, legal, financial and business development expertise of John M. Leonard, M.D., our President and Chief Executive Officer, Glenn Goddard, our Executive Vice President and Chief Financial Officer, José E. Rivera, our Executive Vice President, General Counsel, and Andrew Schiermeier, our Executive Vice President, Corporate Strategy, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment arrangements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be important for our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products using our technology. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies, universities and research institutions for similar personnel. The market for qualified personnel in the biotechnology space generally, and genome editing and gene therapy fields in particular, in and around the Cambridge, Massachusetts area is especially competitive. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Further, some of the qualified personnel that we hire and recruit are not U.S. citizens, and there is uncertainty with regard to their future employment status due to the current U.S. administration’s announced intention of modifying the legal framework for non-U.S. citizens to be employed in the U.S. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

If, in the future, we are unable to establish sales, marketing and distribution capabilities or enter into agreements with third parties to sell, market and distribute products based on our technologies, we may not be successful in commercializing our products if and when any products candidates or therapies are approved and we may not be able to generate any revenue.

We do not currently have a sales, marketing or distribution infrastructure and, as a company, have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force 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 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 sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future product candidates that we may develop;
- the lack of complementary treatments to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the location of patients in need of our product candidates and the treating physicians who may prescribe the products; and
- unforeseen costs and expenses, as well as legal and regulatory requirements, associated with creating and operating a sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will 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 product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Our technological advancements and any potential for revenue may be derived in part from our collaborations with Novartis and Regeneron, and if either of these collaboration agreements were to be terminated or materially altered, our business, financial condition, results of operations and prospects would be harmed.

In December 2014, we entered into a collaboration agreement with Novartis regarding the discovery of new CRISPR/Cas9-based therapies principally using CAR-T cells and HSCs. Under the Novartis collaboration agreement, we received a commitment to advance multiple programs. Pursuant to the Novartis agreement, we granted Novartis exclusive rights to further develop and commercialize products arising out of the CAR-T cell program during the research term. Regarding HSCs, we are jointly advancing multiple programs with Novartis and have agreed to a process for assigning development and ownership rights, which may enable us to develop our own proprietary HSC pipeline.

In April 2016, we entered into a collaboration agreement with Regeneron that includes a product component to research, develop and commercialize CRISPR/Cas-based therapeutic products primarily focused on genome editing in the liver as well as a technology collaboration component, pursuant to which we and Regeneron will engage in research and development activities aimed at discovering and developing novel technologies and improvements to CRISPR/Cas9 technology to enhance our genome editing platform. Pursuant to the Regeneron collaboration agreement, we granted Regeneron exclusive rights to select up to 10 targets, subject to certain restrictions, while we retain the rights to solely develop our initial indications, other than ATTR, which is subject to a co-development and co-promotion agreement with Regeneron. We also have the right to choose additional liver targets for our own development during the collaboration term. In July 2018, we entered into the first co-development and co-promotion agreement directed to ATTR, under which we will be the clinical and commercial lead for ATTR activities.

Either Novartis or Regeneron may change its strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Each of Novartis and Regeneron has a variety of marketed products and product candidates either by itself or under collaboration with other companies, including some of our competitors, and the respective corporate objectives of Novartis or Regeneron may not be consistent with our best interests. If either of our collaboration partners fails to develop, obtain regulatory approval for or ultimately commercialize any product candidate from the development programs governed by the respective collaboration agreement in the applicable territories, or if either of our collaboration partners breaches or terminates our collaboration with it, our business, financial condition, results of operations and prospects could be harmed. In addition, any material alteration of the collaboration agreements, or dispute or litigation proceedings we may have with either Novartis or Regeneron in the future could delay development programs, create uncertainty as to ownership of or access to intellectual property rights, distract management from other business activities and generate substantial expense.

Our existing and future collaborations will be important to our business. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have limited capabilities for product discovery and development and do not yet have any capability for sales, marketing or distribution. Accordingly, we have entered, and plan to enter, into collaborations with other companies, including our therapeutic-focused collaboration agreements with Novartis and Regeneron, that we believe can provide such capabilities. These therapeutic-focused collaborations provide us with important technologies and funding for our programs and technology, and we expect to receive additional technologies and funding under these and other collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may dispute the amounts of payments owed;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- 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 develop independently or with third parties products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- collaborators may fail to comply with applicable legal and regulatory requirements regarding the development, manufacture, sale, distribution or marketing of a product candidate or product;
- collaborators with sale, marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the sale, marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, payment obligations or the preferred course of discovery, development, sales or marketing, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional and burdensome responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend their or our relevant intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation and liability;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination or cessation, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our therapeutic collaborations do not result in the successful discovery, development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development and commercialization of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product discovery, development, regulatory approval and commercialization described in this report also apply to the activities of our therapeutic collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

For some of our programs, we may in the future determine to collaborate with pharmaceutical and biotechnology companies for discovery, development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators because, for example, third-parties have comparable rights to the CRISPR/Cas9 system or similar genome editing technologies. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail discovery efforts or the development of a product candidate, 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 fund and undertake discovery, development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary discovery, development and commercialization activities, we may not be able to further develop our product candidates, bring them to market or continue to develop our technology and our business may be materially and adversely affected.

In vivo ***genome editing products and*** **ex vivo** ***allogeneic engineered cell therapies are novel and may be complex and difficult to manufacture. We could experience manufacturing problems that result in delays in the development or commercialization of our product candidates or otherwise harm our business.***

The manufacturing process used to produce CRISPR/Cas9-based *in vivo* and engineered cell therapy product candidates may be complex, as they are novel and have not been validated for clinical and commercial production. Several factors could cause production interruptions, including equipment malfunctions; facility unavailability or contamination; raw material cost, shortages or contamination; natural disasters; disruption in utility services; human error; insufficient personnel; inability to meet legal or regulatory requirements; or disruptions in the operations of our suppliers.

Our product candidates will require processing steps that are more complex than those required for most small molecule drugs. Moreover, unlike small molecules, the physical and chemical properties of a complex product such as ours generally cannot be fully characterized. As a result, assays of the finished product or relevant components may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we will employ multiple steps to control the manufacturing process to assure that the process works and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and litigation, insufficient inventory or production interruption. We may encounter problems achieving adequate quantities and quality of clinical grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures, product recalls or production interruption. Lot failures, product recalls or production interruption could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

We expect to rely in part on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if the third parties fail to provide us with sufficient quantities of product inputs or fail to do so at acceptable quality levels or prices or fail to meet legal and regulatory requirements.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must eventually rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused any product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in therapies that are safe, potent or effective.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. We will be dependent on our contract manufacturing partners for compliance with legal and regulatory requirements for manufacture, including current good manufacturing practice ("cGMP"), and in certain cases, current good tissue practice ("cGTP"), requirements of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, particularly as we increase the scale of our manufactured material. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We will depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol and other legal, regulatory and scientific standards. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our legal responsibilities. We and these third parties are required to comply with good clinical practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed

unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP, and in certain cases, cGTP, requirements and may require a large number of test patients.

Our failure or any failure by these third parties to comply with these requirements or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates applicable federal, state or local, as well as foreign, laws and regulations, such as the fraud and abuse or false claims laws and regulations or privacy and security laws.

Any third parties conducting our future clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, the transition to a new CRO may result in delays, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Unfavorable global economic conditions or political developments could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, political unrest and global financial crises can cause extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, political unrest or additional global financial crises could result in a variety of risks to our business, including weakened demand for our products, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate, further political developments and financial market conditions could adversely impact our business.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, theft, vandalism, accidental or intentional errors, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure or accident and are not aware of any security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of preclinical or clinical trial data from completed or future preclinical or clinical trials, respectively, could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Risks Related to Government Regulation

While the regulatory framework for approval of gene therapy including genome editing products exists, the lack of specific guidance and precedent for genome-edited products makes the regulatory approval process potentially more unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities. We are not permitted to market any drug or biological product, including *in vivo* products or engineered cell therapies, in the U.S. until we receive regulatory approval from the FDA. We have not previously submitted an BLA to the FDA, or similar approval filings to comparable foreign authorities. An BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective or, for biological products, safe, pure and potent for each desired indication. The application must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-approval inspection by the FDA, or applicable foreign authority, prior to the approval or licensure of the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has not approved any nuclease edited cell therapies for human therapeutic use. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials. Moreover, while we are not aware of any specific genetic or biomarker diagnostic tests for which regulatory approval would be necessary in order to advance any of our product candidates to clinical trials or potential commercialization, in the future regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining and maintaining regulatory authorization to conduct a trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs, clinical trial sites and clinical investigators, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCP requirements or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP regulations for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the DSMB for such trial or the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be impaired. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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 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 grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also authorize the manufacturing, marketing and sale 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 U.S., including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., 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 are allowed 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 fail to comply with the regulatory requirements in international markets or 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 receive regulatory approval of any product candidates or therapies, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, potency, efficacy and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP, and in certain cases, cGTP, requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and, in certain cases, cGTP requirements. 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 BLA, other marketing applications, and previous responses to inspection observations. 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 may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with legal or regulatory requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may seek to impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the U.S. market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory and legal compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, certain policies of the current or future U.S. administration may impact our business and industry. Namely, the current administration has taken, or may take, several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking and issuance of guidance. On January 30, 2017, the U.S. president issued an executive order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. In guidance issued by the Office of Information and Regulatory Affairs within OMB on April 5, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents, and on September 8, 2017, the FDA published notices in the Federal Register soliciting broad public comment to identify regulations that could be modified in compliance with these Executive Orders. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Healthcare cost control initiatives, including healthcare legislative reform measures, 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 U.S. and certain foreign jurisdictions, there have been, and are expected to continue to be, a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In the U.S., however, significant uncertainty exists regarding the provision and financing of health care because the current administration and federal legislators have publicly declared their intention to significantly modify the current legal and regulatory framework for the health care system but details have not been agreed upon or disclosed.

Current legislation at the U.S. federal and state levels seeks to reduce healthcare costs and improve the quality of healthcare. In March 2010, the Affordable Care Act was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical and biotechnology industry. The Affordable Care Act, among other things, subjects biologic products to potential competition by lower-cost biosimilars, addresses 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, increases the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extends the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjects manufacturers to new annual fees and taxes for certain branded prescription drugs and biologic agents and provides incentives to programs that increase the federal government's comparative effectiveness research. At this time, the full effect that the Affordable Care Act would have on our

business remains unclear. Further, significant uncertainty exists regarding the future scope and effect of the Affordable Care Act because the current administration and federal legislators have publicly declared their intention to significantly modify or repeal the legislation. We cannot predict the ultimate form or timing of any modification to, or repeal of, the Affordable Care Act or the effect that such modification or repeal would have on our business. Public announcements by the U.S. administration and members of the U.S. Congress have emphasized the administration's significant interest in pursuing healthcare reform. Such reform efforts and any resulting changes to the Affordable Care Act, or related regulations and laws, could impact our ability to sell our products profitably.

Other legislative changes relevant to the health care system have been adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 percent per fiscal year, which went into effect in April 2013, and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and other treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2017, the U.S. president signed into law the Tax Cuts and Jobs Act ("TCJA"), which among other things, repealed the Affordable Care Act's requirement that all Americans under age 65 have health insurance or pay a financial payment. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, or insured patients generally, which could have a material adverse effect on our future, potential customers and, accordingly, our financial operations.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. As indicated previously, significant uncertainty exists regarding the future scope and effect of current health care legislation and regulations because the current administration and federal legislators have publicly declared their intention to significantly modify or repeal the current legislative framework. We cannot predict the initiatives that may be adopted in the future, any of which could limit or modify the amounts that foreign, federal and state governments as well as private payors, including patients, will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls could harm our business, financial conditions and prospects and may adversely affect:

- the demand for or utilization of our product candidates, if we obtain regulatory approval;
- our ability to 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, fees and rebates that we are required to pay; and
- the availability of capital.

Any denial in coverage or reduction in reimbursement from Medicare or other government programs, including state and foreign programs, may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

Our employees, independent contractors, clinical investigators, CROs, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of non-compliance, fraud, misconduct or other illegal activity by our employees, independent contractors, clinical investigators, CROs, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with federal and state laws and those of other applicable jurisdictions; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and similar foreign privacy or fraudulent misconduct laws; or report financial

information or data accurately; or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with clinical investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare products and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including promotion and marketing of off-label uses of our products, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 significant fines or other sanctions.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws, health information privacy and security laws and anti-corruption laws. If we are unable to comply, or have not fully complied, with such laws or their relevant foreign counterparts, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly, or indirectly through our future, potential customers and third-party payors, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws or their relevant foreign counterparts may impact, among other things, our proposed sales, marketing, and education programs and our relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient privacy regulation by the federal government and the states in the U.S. as well as other jurisdictions. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities 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, arrangement for or recommendation of the purchase, lease, order, arrangement for 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 Patient Protection and Affordable Care Act, or Affordable Care Act or ACA, provides 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 federal False Claims Act and the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes criminal and civil liability for 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. Similar to the federal Anti-Kickback Statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which 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;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” created under the Affordable Care Act, and their implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members;
- the Foreign Corrupt Practices Act (“FCPA”) and other laws which prohibit improper payments or offers of payments to foreign governments and their officials and political parties by U.S. persons and issuers as defined by the statute for the purpose of obtaining or retaining business; and
- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the commercialization of adulterated or misbranded of drugs and medical devices and the Public Health Service Act, which prohibits, among other things, the commercialization of biological products unless a biologics license is in effect.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

Because of the breadth of these laws and the limited statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

As of May 25, 2018, the General Data Protection Regulation (“GDPR”) regulates the collection and use of personal data in the EU. The GDPR covers any business, regardless of its location, that provides goods or services to residents in the EU and, thus, could incorporate our activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for “sensitive information,” which includes health and genetic information of individuals residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU to regions that have not been deemed to offer “adequate” privacy protections, such as the U.S. currently. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, which may deviate slightly from the GDPR, may result in warning letters, mandatory audits and financial penalties, including fines of up to 4 percent of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is unclear whether the authorities will conduct random audits of companies doing business in the EU, or act solely after complaints are filed claiming a violation of the GDPR. The lack of compliance standards and precedent, enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects.

The increasingly global nature of our business operations subjects us to domestic and foreign anti-bribery and anti-corruption laws and regulations, such as the FCPA. Activities conducted in jurisdictions outside of the U.S. create the risk of unauthorized payments or offers of payments that are prohibited under the FCPA or comparable laws and regulations. It is our policy to implement safeguards to discourage these practices by our employees. However, these safeguards may ultimately prove ineffective, and our employees, consultants, and agents may engage in conduct for which we might be held responsible. Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations as well as other domestic and foreign legal requirements will 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 U.S. federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring 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 U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we fail to comply with environmental, health and safety, and laboratory animal welfare laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous federal, state and local environmental, health and safety, and laboratory animal welfare laws and regulations. These legal requirements include those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes as well as those which regulate the care and use of animals in research. Our operations will involve research using research animals and the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety, and laboratory animal welfare laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Our Intellectual Property

Third-party claims of intellectual property infringement against us, our licensors or our collaborators may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the valid patents and proprietary rights of third parties.

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 industry, government, academia and other biotechnology and pharmaceutical research expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our technology, future product candidates or the use of such product candidates do not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications. Because patent rights are granted jurisdiction-by-jurisdiction, our freedom to practice certain technologies, including our ability to research, develop and commercialize our product candidates, may differ by country.

Third parties may assert that we infringe their patents or that we are otherwise employing their proprietary technology without authorization, and may sue us. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover product candidates we discover and develop. 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 may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies or the manufacture, use or sale of our product candidates infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, the holders of any such patents may be able to block our ability to commercialize the applicable product candidate 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. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Third parties may seek to claim intellectual property rights that encompass or overlap with intellectual property that we own or license from them or others. Legal proceedings may be initiated to determine the scope and ownership of these rights, and could result in our loss of rights, including injunctions or other equitable relief that could effectively block our ability to further develop and commercialize our product candidates. For example, through our 2014 license agreement with Caribou, we sublicense the rights of the Regents of the University of California and the University of Vienna (collectively, “UC/Vienna”) to a worldwide patent portfolio that covers methods of use and compositions relating to engineered CRISPR/Cas9 systems for, among other things, cleaving or editing DNA and altering gene product expression in various organisms, including eukaryotic cells. We sublicense the UC/Vienna rights to this portfolio for human therapeutic, prophylactic and palliative uses, including companion diagnostics, except for anti-fungal and anti-microbial uses. This patent portfolio to-date includes, for example, multiple granted, allowed, and/or allowable patent applications in the U.S., as well as granted patents from the European Patent Office, the United Kingdom’s Intellectual Property Office, the German Patent and Trade Mark Office, Australia’s Intellectual Property agency and China’s Intellectual Property Office. Because UC/Vienna co-own this portfolio with Dr. Emmanuelle Charpentier (from whom we do not have sublicense rights), we refer to this co-owned worldwide patent portfolio as the UC/Vienna/Charpentier patent family. UC/Vienna could challenge Caribou’s rights under their license agreement, including Caribou’s right to sublicense its rights to others, such as Intellia, and on what terms such a sublicense would be granted, each of which could adversely impact our rights under our license agreement with Caribou.

Similarly, Caribou could challenge the scope of our licensed rights or fields under our license agreement, which could adversely impact our exclusive rights to use CRISPR/Cas9 technology in our human therapeutics field. On October 17, 2018, we initiated an arbitration proceeding against Caribou asserting that it is violating the terms and conditions of the Caribou License, as well as other contractual and legal rights, by using and seeking to license to third parties two patent families relating to specific structural or chemical modifications of guide RNAs, purportedly invented or controlled by Caribou, in our exclusive human therapeutic field. Under the Caribou License, Caribou granted to the Company a worldwide, exclusive license to all of Caribou’s intellectual property relating to CRISPR/Cas9 technology for all therapeutic, prophylactic and palliative uses and applications for any or all diseases and conditions in humans with the sole exceptions of anti-microbial and/or anti-fungal applications. The license encompassed all CRISPR/Cas9 intellectual property developed or controlled by Caribou as of July 16, 2014 and through an IP cutoff date (January 30, 2018) that was necessary or useful for us to develop, manufacture or commercialize products in our field, as well as any technology developed by Caribou under a service agreement entered into by the Company and Caribou in July 2014. Caribou has asserted that the two families of intellectual property are outside the scope of our license. In accordance with the Caribou License, we have submitted a demand for arbitration seeking a declaration that the disputed intellectual property is included within the scope of our license under the Caribou License, an award of compensatory, consequential and punitive damages based on Caribou’s conduct, and an injunction prohibiting Caribou from licensing or using this intellectual property in our exclusive human therapeutics field, among other claims.

In addition, third parties could assert that UC/Vienna/Charpentier do not have rights to the CRISPR/Cas9 technology, or that any rights owned by UC/Vienna/Charpentier are limited. For example, the Broad Institute, Massachusetts Institute of Technology, the President and Fellows of Harvard College and the Rockefeller University (collectively, the "Broad Institute") co-own patents and patent applications (collectively, the "Broad Institute patent family") that also claim certain aspects of CRISPR/Cas9 systems to edit genes in eukaryotic cells, including human cells. Because the respective owners of a UC/Vienna/Charpentier patent application and the Broad Institute patent family both allege owning intellectual property claiming overlapping aspects of CRISPR/Cas9 systems and methods to edit genes in eukaryotic cells, including human cells, our ability to market and sell CRISPR/Cas9-based human therapeutics may be adversely impacted depending on the scope and actual ownership over the inventions claimed in the competing patent portfolios. In January 2016, an interference proceeding was declared in the U.S. Patent and Trademark Office ("USPTO") between the claims from one UC/Vienna/Charpentier patent application we sublicense through Caribou and certain U.S. patents and one application of the Broad Institute patent family to determine which set of inventors invented first and, thus, is entitled to patents on the invention in the U.S. In February 2017, the Patent Trial and Appeal Board ("PTAB") dismissed the interference proceeding finding that the respective patent claims involved in the interference were distinct such that they did not meet the legal requirement to proceed with the interference. The PTAB did not make any decision regarding inventorship or priority, and therefore ownership, of the inventions claimed by the patents and applications at issue. UC/Vienna/Charpentier appealed to the U.S. Court of Appeals for the Federal Circuit seeking a review and reversal of the PTAB's decision to terminate the interference. On September 10, 2018, the Federal Circuit affirmed the PTAB's decision to terminate the interference proceeding. In addition, several other parties also claim and are seeking intellectual property rights that could overlap with aspects of the CRISPR/Cas9 inventions covered by the UC/Vienna/Charpentier patent portfolio, which could result in other legal proceedings, including interference proceedings, to determine the ownership and scope of the inventions claimed by each party including UC/Vienna/Charpentier. If UC/Vienna/Charpentier are unable to prevail in their inventorship claims or if the scope of their claims is narrowed through these various legal proceedings, then we could be prevented from developing and commercializing all or some of our products candidates unless we can obtain rights to the third-parties' intellectual property, or avoid or invalidate it.

Third parties could also assert patent rights against us to seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize product candidates. For example, the Broad Institute or other third-parties that own issued patents, including patents claiming aspects of the CRISPR-Cas9 technology, could seek to assert such patents against us claiming that our activities, including those relating to the CRISPR-Cas9 technology, infringe their respective patents. Defense of these or similar claims, regardless of their merit, would involve substantial legal expense, 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 have to pay substantial damages, including treble damages and attorneys' fees for any adjudicated willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In that event, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties asserting their patent rights against us may seek and obtain injunctive or other equitable relief, which could effectively limit or block our ability to further develop and commercialize our product candidates. If we are found to infringe a third party's valid intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing, manufacturing or importing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing one or more of our product candidates, force us to redesign our infringing products or force us to cease some or all of our business operations, any of which could materially harm our business and could prevent us from further developing and commercializing our proposed future product candidates thereby causing us significant harm. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Intellectual property owned by third parties relating to CRISPR/Cas9 or other related technologies necessary to develop, manufacture and commercialize viable CRISPR/Cas9 therapeutics – such as compositions of the products or components, methods of treatment, delivery technologies, chemical modifications, and analytical and manufacturing methods – could adversely impact our ability to ultimately market and sell products. Third parties may own intellectual property, including patents, that cover all or aspects of our technologies and potential products, and may be necessary for us to develop or commercialize viable products. If we are unable to successfully license, avoid or challenge such third-party intellectual

property, we may not be able to develop and commercialize viable products in all or certain jurisdictions. In addition, if the intellectual property covering our products or technologies that we own or license were to be legally impaired or lost, we may be unable to realize sufficient financial returns to support the development or commercialization of our products. For additional information regarding the risks that may apply to our and our licensors' intellectual property rights, see the section entitled "Risks Related to Our Intellectual Property" appearing elsewhere in this report for more information.

Under our license agreement with Caribou, we sublicense a patent family from The Regents of the University of California and the University of Vienna that is co-owned by Dr. Emmanuel Charpentier. The outcome of recent proceedings, as well as potential future proceedings, related to this patent family may affect our ability to utilize the intellectual property sublicensed under our license agreement with Caribou.

The Broad Institute patent family includes issued patents in the U.S. and Europe that purport to cover certain aspects of the CRISPR/Cas9 genome editing platform for use on eukaryotic cells, including human cells. On January 11, 2016, the PTAB declared an interference proceeding between certain patents and a patent application of the Broad Institute patent family and one UC/Vienna/Charpentier patent application to determine, based on priority of invention, whether the contested inventions belong either to UC/Vienna/Charpentier or to the Broad Institute in the U.S. This interference proceeding was discontinued by the PTAB in February 2017 without any finding regarding inventorship or priority. In discontinuing the interference proceeding, the PTAB found that the claim sets presented by the two parties were "patentably distinct" from each other and, thus, did not meet the statutory requirements for continuing the proceeding. In April 2017, UC/Vienna/Charpentier appealed to the U.S. Court of Appeals for the Federal Circuit seeking a review and reversal of the PTAB's decision to terminate the interference. On September 10, 2018, the Federal Circuit issued a ruling affirming the PTAB's decision to terminate the interference proceeding. In addition, UC/Vienna/Charpentier continue to prosecute other patent claims covering the CRISPR/Cas9 inventions, which could also result in allowable or issued patents in the U.S. Certain of the claims being prosecuted by UC/Vienna/Charpentier, if found allowable by the USPTO, could lead to interference proceedings against patents or patent applications owned by other parties, including the Broad Institute patent family, with respect to certain claims expressly relating to the use of CRISPR/Cas9 in eukaryotic cells. We cannot be certain which of these results, if any, will actually occur. Further, the effects that any such results may have on us and our intellectual property position, including whether UC/Vienna/Charpentier will ultimately be successful in prosecuting to issuance a patent covering the CRISPR/Cas9 system that we are able to use under our license agreement with Caribou, are currently unknown. The Broad could seek to assert its issued patents against us based on our CRISPR/Cas9-based activities, including commercialization. Defense of these claims, regardless of their merit, would involve substantial litigation expense, 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 have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In that event, we could be unable to further develop and commercialize our product candidates, which could harm our business significantly.

In addition, other third parties, such as Vilnius University, ToolGene, Inc., MilliporeSigma (a subsidiary of Merck KGaA) and Harvard University, filed patent applications claiming CRISPR/Cas9-related inventions around or within a year after the UC/Vienna/Charpentier application was filed and may allege that they invented one or more of the inventions claimed by UC/Vienna/Charpentier before UC/Vienna/Charpentier. If the USPTO deems the scope of the claims of one or more of these parties to sufficiently overlap with the allowable claims from the UC/Vienna/Charpentier application, the USPTO could declare other interference proceedings to determine the actual inventor of such claims. In addition, UC/Vienna/Charpentier or the other third parties could seek judicial review of their inventorship claims. If UC/Vienna/Charpentier fail in defending their inventorship priority on any of these claims, we may lose valuable intellectual property rights, such as the exclusive right to use, such intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, any disputes could result in substantial costs and be a distraction to management and other employees.

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

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor or other claims challenging the inventorship of our patents or ownership of our intellectual property (including patents and intellectual property that we in-license). For example, the UC/Vienna/Charpentier patent family that is covered by our license agreement with Caribou is co-owned by UC/Vienna and Dr. Charpentier, and our sublicense rights are derived from the first two co-owners and not from Dr. Charpentier. Therefore,

our rights to these patents are not exclusive and third parties, including competitors, may have access to intellectual property that is important to our business. In addition, we may have inventorship disputes arise from conflicting obligations of collaborators, consultants or others who are involved in developing our technology and product candidates. Litigation or other legal proceedings may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We depend on intellectual property licensed from third parties and termination or modification of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others, including Caribou and Novartis. Any termination of these licenses, loss by our licensors of the rights they receive from others, diminution of our rights or those of our licensors, or a finding that such intellectual property lacks legal effect, could result in the loss of significant rights and could harm our ability to commercialize any product candidates. For example, UC/Vienna could challenge Caribou's rights under their agreement, including Caribou's right to sublicense its rights to others, such as Intellia, and on what terms such a sublicense would be granted, each of which could adversely impact our rights under our agreement with Caribou. Similarly, Caribou or other licensors, or other third parties from which we derive rights, could challenge the scope of our licensed rights or fields under our license agreement, which could adversely impact our exclusive rights to use CRISPR/Cas9 technology in our human therapeutics field.

On October 17, 2018, we initiated an arbitration proceeding against Caribou asserting that it is violating the Caribou License, as well as other contractual and legal rights, by using and seeking to license to third parties two patent families relating to specific structural or chemical modifications of guide RNAs, that were purportedly invented or controlled by Caribou, in our exclusive human therapeutic field. Under the Caribou License, Caribou granted to the Company a worldwide, exclusive license to all of Caribou's intellectual property relating to CRISPR/Cas9 technology for all therapeutic, prophylactic and palliative uses and applications for any or all diseases and conditions in humans with the sole exceptions of anti-microbial and/or anti-fungal applications. The license encompassed all CRISPR/Cas9 intellectual property developed or controlled by Caribou as of July 16, 2014 and through an intellectual property cutoff date (January 30, 2018) that was necessary or useful for the Company to develop, manufacture or commercialize products in its field, as well as any technology developed by Caribou under a service agreement entered into by the Company and Caribou in July 2014. Caribou has asserted that the two families of intellectual property are outside the scope of our license. In accordance with the Caribou License, we have submitted a demand for arbitration seeking a declaration that the disputed intellectual property is included within the scope of our license under the Caribou License, an award of compensatory, consequential and punitive damages based on Caribou's conduct, and an injunction prohibiting Caribou from licensing or using this intellectual property in our exclusive human therapeutics field, among other claims.

Disputes have and may arise between us and our licensors, our licensors and their licensors, or us and third parties that co-own intellectual property with our licensors or their licensors, regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology, products and processes infringe on, or derive from, intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement, or whether they are compliant with their contractual obligations to their respective licensor(s);
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties, including those under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;

- our involvement in the prosecution, defense and enforcement of the licensed patents and our licensors' overall patent strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and
- the amounts of royalties, milestones or other payments due under the license agreement.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend and enforce patents and patent applications that are material to our business.

Patents relating to our product candidates are controlled by certain of our licensors or their respective licensors. Each of our licensors or their licensors generally has rights to file, prosecute, maintain and defend the patents we have licensed from such licensor. If these licensors or any future licensees and in some cases, co-owners from which we do not yet have licenses, having rights to file, prosecute, maintain, and defend our patent rights fail to adequately conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. We cannot be certain that such activities by our licensors or their respective licensors have been or will be conducted in compliance with applicable laws and regulations or in our best interests, or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as the co-owners of the intellectual property from which we have not yet obtained a license. We cannot be certain that our licensors or their licensors, and in some cases, their respective co-owners, will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. For example, with respect to our sublicensed rights from Caribou to UC/Vienna/Charpentier intellectual property, UC retained the right to control the prosecution, enforcement and defense of this intellectual property in its license agreement with Caribou and, pursuant to an Invention Management Agreement, shares these responsibilities with CRISPR Therapeutics and, under certain circumstances, ERS, as the designated managers of the intellectual property. For these reasons, UC may be unable or unwilling to prosecute certain patent claims that would be best for our product candidates, or enforce its patent rights against infringers of the UC/Vienna/Charpentier patent family.

Even if we are not a party to legal actions or other disputes involving our licensed intellectual property, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control.

We may not be successful in obtaining or maintaining necessary rights to product components and processes or other technology for our product development pipeline.

The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates, delivery systems or technologies that may require the use of additional proprietary rights held by third parties. Our ultimate product candidates may also require specific modifications or formulations to work effectively and efficiently. These modifications or formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

If we are unable to successfully obtain rights to valid third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates, or asserting and defending our intellectual property rights that protect our products and technologies.

We anticipate that we will file additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- the scope, degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether certain governments will appropriate our intellectual property rights and allow competitors to use them; or
- whether we will need to initiate litigation or administrative proceedings to assert or defend our patent rights, which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that any claims in our pending or future patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our ultimately issued patents will be considered valid and enforceable by courts in the U.S. or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in-license may fail to result in issued patents with claims that cover any product candidates or uses thereof in the U.S. or in other foreign countries.

Further, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. We may also require the cooperation of our licensors or other necessary parties, such as the co-owners of the intellectual property from which we have not yet obtained a license, in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we will be unable to know with certainty whether we were the first to make any inventions claimed in any patents or patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. There is a substantial amount of litigation as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO and oppositions and other comparable proceedings in foreign jurisdictions, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, and we expect this to be true for the CRISPR/Cas9 space as well. For example, a number of third parties have filed oppositions challenging the validity, and seeking the revocation, of the CRISPR/Cas9 genome editing patents granted to UC/Vienna/Charpentier by the European Patent Office to date.

In addition, since the passage of the America Invents Act in 2013, U.S. law also provides for other procedures to challenge patents, including *inter partes* reviews and post-grant reviews, that add uncertainty to the possibility of challenge to our developed or licensed patents and patent applications in the future. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. See the above risk factor titled "*Third-party claims of intellectual property infringement against us, our licensors or our collaborators may prevent or delay our product discovery and development efforts*."

Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to practice the invention or stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market product candidates under patent protection would be reduced. Because patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

Our pending and future patent applications or the patent applications that we obtain rights to through in-licensing arrangements may not result in patents being issued which protect our technology or future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Litigation or other administrative proceedings challenging our intellectual property, including interferences, derivation, reexamination, *inter partes* reviews and post-grant reviews, may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. Furthermore, there could be public announcement of the results of hearings, motions or other interim proceedings or developments in any proceeding challenging the issuance, scope, validity and enforceability of our developed or licensed intellectual property. 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.

Any of these potential negative developments could impact the scope, validity, enforceability or commercial value of our patent rights and, as a result, have material adverse effect on our business, financial condition, results of operations or prospects.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent. We also utilize proprietary processes for which patents are difficult to enforce. In addition, other elements of our product discovery and development processes involve proprietary know-how, information, or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can have a different scope and strength than do those in the U.S. In addition, the laws of some foreign countries, such as China, Brazil, Russia, India, and South Africa, do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 rights are not as strong as those in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing. In addition, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Further, patients may choose to travel to countries in which we do not have intellectual property rights or which do not enforce these rights to obtain the products or treatment from competitors in such countries.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China, Brazil, Russia, India, and South Africa, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our

efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our licenses, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding or a declaratory judgment action against us, a court may decide that one or more of our patents is not valid or is unenforceable, 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 or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Further, if a party to our licenses, either a licensee or licensor, were to breach or challenge our rights under the relevant license agreement (or if one of our licensor's own licensors were to challenge our licensor's rights), we may have to initiate or participate in a legal proceeding to enforce our rights. Any such legal proceeding could be expensive and time-consuming. In addition, if a court or other tribunal were to rule against us, we could lose key intellectual property and financial rights. Pursuing or defending against these legal claims, regardless of merits, would involve substantial legal expense and would be a substantial diversion of employee resources from our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or contractual litigation there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceeding. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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. For example, as explained above in the section entitled "***We depend on intellectual property licensed from third parties and termination or modification of any of these licenses could result in the loss of significant rights, which would harm our business",*** on October 17, 2018, we initiated an arbitration proceeding against Caribou asserting that it is violating the Caribou License, as well as other contractual and legal rights, by using and seeking to license to third parties two patent families relating to specific structural or chemical modifications of guide RNAs, that were purportedly invented or controlled by Caribou, in our exclusive human therapeutic field. In accordance with the Caribou License, we have submitted a demand for arbitration seeking a declaration that the disputed intellectual property is included within the scope of our license under the Caribou License, an award of compensatory, consequential, and punitive damages based on Caribou's conduct, and an injunction prohibiting Caribou from licensing or using this intellectual property in our exclusive human therapeutics field, among other claims.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or other jurisdictions, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity, unpatentability and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies as well as academic research institutions. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims, which could result in money damages or a judicial order prohibiting the use of certain intellectual property. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be required to pay certain milestones and royalties under our license agreements with third-party licensors.

Under our current and future license agreements, we may be required to pay milestones and royalties based on our revenues, including sales revenues of our products, utilizing the technologies licensed or sublicensed from third parties, including Caribou, Novartis and Regeneron, and these milestones and royalty payments could adversely affect our ability to research, develop and obtain approval of product candidates, as well as the overall profitability for us of any products that we may seek to commercialize. In order to maintain our license rights under these license agreements, we will need to meet certain specified milestones, subject to certain cure provisions, in the development of our product candidates. Further, our licensors (or their licensors) or licensees may dispute the terms, including amounts, that we are required to pay under the respective license agreements. If these claims were to result in a material increase in the amounts that we are required to pay to our licensors, or in a claim of breach of the license, our ability to research, develop and obtain approval of product candidates, or to commercialize products, could be significantly impaired.

In addition, these agreements contain diligence milestones and we may not be successful in meeting all of the milestones in the future on a timely basis or at all. We will need to outsource and rely on third parties for many aspects of the clinical development, sales and marketing of our products covered under our license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with their third-party licensors.

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.

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 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 future, potential customers in our markets of interest. At times, competitors 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 unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and 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 impact our financial condition or results of operations.

Risks Related to Our Common Stock

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

In May 2016, we closed our initial public offering. Prior to this offering, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on the Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The price of our common stock historically has been volatile, which may affect the price at which you could sell any shares of our common stock.

The market price for our common stock historically has been highly volatile and could continue to be subject to wide fluctuations in response to various factors. This volatility may affect the price at which you could sell the shares of our common stock, and the sale of substantial amounts of our common stock could adversely affect the price of our common stock. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including:

- the success of our or competing products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- developments or disputes concerning patent applications, issued patents or other intellectual property rights;
- regulatory or legal developments in the U.S. and other countries;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- public perception of the safety of genome editing based therapeutics;
- general economic, industry and market conditions; and
- the other factors described in this *Risk Factors* section.

In addition, companies trading in the stock market in general, and in the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our principal stockholders and management own a significant percentage of our stock and, if they choose to act together, will be able to control or exercise significant influence over matters subject to stockholder approval.

As of June 30, 2018, our executive officers, directors, five percent or greater stockholders and their affiliates beneficially own approximately 67.1% of our outstanding voting stock. These stockholders may have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

We have broad discretion over the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending our use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of stockholders and could cause our stock price to fall.

The Company will need additional capital in the future to continue our planned operations in addition to the proceeds we received from our initial public offering in May 2016 and follow-on public offering in November 2017. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to the Company's existing stockholders, and new investors could gain rights superior to our existing stockholders.

On October 12, 2018, we filed a shelf registration statement (the "Shelf Registration Statement"), under which we may, from time to time, sell our common stock, convertible securities or other equity securities in one or more offerings. The Shelf Registration Statement permits: (i) the offering, issuance and sale by us of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; and (ii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement ("ATM"), with Jefferies LLC. Sales of common stock, convertible securities or other equity securities by us or our stockholders under the Shelf Registration Statement may represent a significant percentage of our common stock currently outstanding. If we or our stockholders sell, or the market perceives that we or our stockholders intend to sell, substantial amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

In addition, sales of a substantial number of shares of our outstanding common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock that many of them are now able to sell in the public market. Significant portions of these shares are held by a relatively small number of stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.

Provisions of our certificate of incorporation and by-laws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and by-laws:

- permit the board of directors to issue up to 5,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes;
- provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders, and may not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;
- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- require that, to the fullest extent permitted by law, a stockholder reimburse us for all fees, costs and expenses incurred by us in connection with a proceeding initiated by such stockholder in which such stockholder does not obtain a judgment on the merits that substantially achieves the full remedy sought;
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer (or president, in the absence of a chief executive officer) or by the board of directors; and
- provide that stockholders will be permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be 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 certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our by-laws, any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company" under applicable SEC regulations, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market 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. Our management and other personnel devote a substantial amount of time to these compliance initiatives.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Under the statute, we cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2020; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We will become a large accelerated filer for the fiscal year ending December 31, 2019, and as such we will lose emerging growth status on December 31, 2018. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Commencing December 31, 2018, we will no longer be an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies will no longer apply to us.

We are currently an emerging growth company but because as of June 30, 2018, the market value of our common stock that was held by non-affiliates exceeded $700 million, we will no longer qualify for such status commencing December 31, 2018. As a large-accelerated filer, we will be subject to certain disclosure requirements that are applicable to other public companies that have not been applicable to us as an emerging growth company. These requirements include:

- compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may not publish an adequate amount of research on the Company, which may negatively impact the trading price for our stock. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. Further, if our operating results fail to meet the forecasts of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We could be subject to significant legal proceedings which may adversely affect our results of operations or financial condition.

We are subject to the risk of litigation, derivative claims, securities class actions, regulatory and governmental investigations and other proceedings, including proceedings arising from investor dissatisfaction with us or our performance. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If any claims were brought against us and resulted in a finding of substantial legal liability, the finding could materially adversely affect our business, financial condition or results of operations or cause significant reputational harm to us, which could seriously adversely impact our business. Allegations of improper conduct by private litigants or regulators, regardless of veracity, may harm our reputation and adversely impact our ability to grow our business. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Changes in tax law may adversely affect our business and financial condition.

The laws and rules dealing with U.S. federal, state and local income taxation are routinely being reviewed and modified by governmental bodies, officials and regulatory agencies, including the Internal Revenue Service and the U.S. Treasury Department. Since the Company was founded in 2014, many such changes have been made and changes are likely to continue to occur in the future. For example, in December 2017, the U.S. president signed into law the TCJA that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and effectuates the migration from a "worldwide" system of taxation to a territorial system. Our net deferred tax assets and liabilities were revalued in December 2017 at the then newly enacted U.S. corporate rate. The impact of this tax reform is uncertain and could be adverse. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, that could result in an increase in our or our shareholders' tax liability.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, 2017, we had federal and state net operating loss carryforwards of $36.7 million and $27.8 million, respectively, which begin to expire in 2034. As of December 31, 2017, we had federal and state research and development tax credit carryforwards of approximately $3.4 million and $2.5 million, which begin to expire in 2034 and 2030, respectively. Our net deferred tax assets and liabilities have been revalued at the newly enacted U.S. corporate rate. Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of our initial public offering in May of 2016 , follow-on offerings and/or subsequent shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOLs and R&D tax credits to offset such taxable income and income tax, respectively, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes. Under the TCJA, net operating losses generated after December 31, 2017 are not subject to expiration but can only offset 80 percent of taxable income in the year that they are used.

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

None.

Item 6. Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

10.1#	Letter Agreement, dated as of July 20, 2018, by and between the Company and Regeneron Pharmaceuticals, Inc. and the corresponding Form of Co-Development and Co-Promotion Agreement, by and between the Company and Regeneron Pharmaceuticals, Inc. (1)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (1)
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (1)
32.1	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by John M. Leonard, M.D., President and Chief Executive Officer of the Company, and Glenn Goddard, Executive Vice President, Chief Financial Officer of the Company. (1)
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Filed with this Form 10-Q.

Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

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.

Dated: October 31, 2018

INTELLIA THERAPEUTICS, INC.

By: /s/ John M. Leonard
John M. Leonard, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Glenn Goddard
Glenn Goddard
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

CONFIDENTIAL

REGENERON PHARMACEUTICALS, INC.
777 Old Saw Mill River Road
Tarrytown, New York 10591

INTELLIA THERAPEUTICS, INC.
40 Erie St., Suite 130
Cambridge, Massachusetts 02139

July 20, 2018

On April 11, 2016, Regeneron Pharmaceuticals, Inc. ("Regeneron") and Intellia Therapeutics, Inc. ("Intellia") entered into a License and Collaboration Agreement (the "Collaboration Agreement"). Under the Collaboration Agreement, the Parties agreed to collaborate to research and develop improvements to CRISPR-Cas technology and to engage in a research and development program in which they will research and develop CRISPR Products Directed to certain Targets. In addition, each Party granted to the other Party certain options to enter into a worldwide cost and profit share arrangement for the development and commercialization of certain CRISPR Products and to enter into a Co-Co Agreement related thereto. Pursuant to Section 5.3 of the Collaboration Agreement, the Parties agreed to negotiate the terms of a Form of Co-Co Agreement. Having agreed to the Form of Co-Co Agreement, the Parties desire to enter into this letter agreement (this "Letter Agreement"), as of July 20, 2018 (the "Effective Date") regarding the Form of Co-Co Agreement. Except as explicitly stated in this Letter Agreement (excluding Exhibit A), capitalized terms used but not defined in this Letter Agreement will have the meaning ascribed to them in the Collaboration Agreement.

The Parties hereby agree that the Form of Co-Development and Co-Promotion Agreement attached hereto as Exhibit A will be the Form of Co-Co Agreement for all purposes contemplated by the Collaboration Agreement. Promptly after the Regeneron Option Exercise Notice or Intellia Option Exercise Notice, as applicable, is delivered to the other Party in accordance with Section 5.1(e)(i) or Section 5.2(c)(i) of the Collaboration Agreement, respectively, the Parties will execute a Co-Development and Co-Promotion Agreement covering the applicable Regeneron Target or Intellia Liver Target [***].

The Parties agree that, subject to the exceptions in Section 13.2 of the Collaboration Agreement, this Letter Agreement (including Exhibit A) is Confidential Information of both Parties under the Collaboration Agreement. The Parties do not intend to issue a press release announcing the execution of this Letter Agreement. Section 13.5(a) of the Collaboration Agreement, excluding the first sentence, and Sections 13.5(b) and 13.5(c) of the Collaboration Agreement, each applied *mutatis mutandis*, are hereby incorporated by reference into this Letter Agreement.

Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. Therefore, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Letter Agreement (including, for clarity, the Form of Co-Development and Co-Promotion Agreement attached hereto as Exhibit A) with the United States Securities and Exchange Commission or its equivalent (the "SEC"). The Parties agree that the form of the redacted version of this Letter Agreement (the "Redacted Letter Agreement"), which shall be mutually agreed by the Parties in good faith within [***], may be used as its filing (or submission) of this Letter Agreement to the SEC, and the Parties shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential information (including any information that constitutes a trade secret or a sensitive commercial term), including with respect to any comments received from the SEC with respect to the proposed redactions. The Parties further agree that, following the initial filing (or submission) of the Redacted Letter Agreement, the filing Party will (i) promptly deliver to the non-filing Party any written correspondence received by the filing Party or its representatives from the SEC with respect to such confidential treatment request and promptly advise the non-filing Party of any other communications between the filing Party or its representatives with the SEC with respect to such confidential treatment request, allowing a reasonable time for the non-filing Party to review and comment; (ii) upon the written request of the non-filing Party, request an appropriate extension of the term of the confidential treatment period; and (iii) if the SEC requests any changes to the redactions set forth in the Redacted Letter Agreement, to the extent reasonably practicable, not agree to any changes to the Redacted Letter Agreement without first discussing such changes with the non-filing Party and taking the non-filing Party's comments into consideration when deciding whether to agree to such changes. In addition, each Party will provide the other Party with an advance copy of any securities filings in which the Letter Agreement is discussed or disclosed, in each case only to the extent describing this Letter Agreement or referencing the other Party, allowing a reasonable time for the other Party to review and comment, and will reasonably consider and, to the extent permitted by a Governmental Authority, or Applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are or will be traded), incorporate the other Party's timely comments thereon [***].

The Parties agree that the provisions of Article 17 of the Collaboration Agreement, applied *mutatis mutandis*, are hereby incorporated by reference into this Letter Agreement.

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, Regeneron and Intellia have caused this Letter Agreement to be executed by their duly authorized representatives as of the Effective Date.

REGENERON PHARMACEUTICALS, INC.

By /s/ Kerry K. Reinersten, Ph.D.
Name: Kerry K. Reinertsen, Ph.D.
Title: Vice President, Strategic Alliances

INTELLIA THERAPEUTICS, INC.

By /s/ John Leonard
Name: John Leonard
Title: Chief Executive Officer

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT A

FORM OF CO-DEVELOPMENT AND CO-PROMOTION AGREEMENT

EXECUTION COPY
CONFIDENTIAL

FORM OF CO-DEVELOPMENT AND CO-PROMOTION AGREEMENT

By and Between

REGENERON PHARMACEUTICALS, INC.

and

INTELLIA THERAPEUTICS, INC.

[_____] [__], [___]

[1] NTD: To be deleted prior to execution of the Agreement for the applicable Co-Funding Target.

FORM OF CO-DEVELOPMENT AND CO-PROMOTION AGREEMENT

THIS FORM OF CO-DEVELOPMENT AND CO-PROMOTION AGREEMENT (this "Agreement"), dated as of [_____] [___], [___] (the "Effective Date"), is by and between REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron"), and INTELLIA THERAPEUTICS, INC., a corporation organized under the laws of Delaware and having a principal place of business at 40 Erie St., Suite 130, Cambridge, Massachusetts 02139 ("Intellia") (with each of Regeneron and Intellia referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, the Parties have entered into that certain License and Collaboration Agreement, dated April 11, 2016 (the "Collaboration Agreement"), whereby the Parties agreed to collaborate to research and develop improvements to CRISPR-Cas (as defined below) technology and to engage in a research and development program in which they will research and develop CRISPR Products Directed to certain Targets (as each such term is defined below);

WHEREAS, under the terms of the Collaboration Agreement, each Party granted to the other Party certain options to enter into a worldwide cost and profit share arrangement for the development and commercialization of certain CRISPR Products;

WHEREAS, the Parties have entered into a Letter Agreement, dated July 20, 2018, whereby the Parties agreed to a Form of Co-Development and Co-Promotion Agreement ("Form of Co-Co Agreement"); and

WHEREAS, this Agreement shall govern the relationship between the Parties with respect to the worldwide cost and profit share arrangement for the development and commercialization of the applicable Co-Funding Products Directed to the applicable Co-Funding Target that is the subject of a Party's option exercised under and in accordance with the Collaboration Agreement.

NOW, THEREFORE, in consideration for the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Affiliate" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.2 "Anti-Corruption Laws" shall have the meaning ascribed to such term in the Collaboration Agreement.

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1.3 "Anticipated First Commercial Sale" shall mean, with respect to a Co-Funding Product, the date agreed upon in advance by the JSC as the expected date of First Commercial Sale of such Co-Funding Product in such country or Region (as applicable) of the world if specified or, otherwise, any country in the world. [***].

1.4 "API" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.5 "Applicable Law" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.6 "Approval" shall mean, with respect to each Co-Funding Product, any approval, registration, license or authorization from an applicable Regulatory Authority required for the Development, Manufacture or Commercialization of such Co-Funding Product in a regulatory jurisdiction, and shall include any such approval, registration, license or authorization granted for any Marketing Approval.

1.7 "Biosimilar Application" shall mean an application or submission filed with a Regulatory Authority for Marketing Approval of a pharmaceutical or biological product claimed to be biosimilar or interchangeable to any Co-Funding Product or otherwise relying on the approval of such Co-Funding Product, including, for example, an application filed under 42 U.S.C. §262(k).

1.8 "BPCIA" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.9 "Business Day" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.10 "Caribou-Intellia License Agreement" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.11 "Change of Control" shall mean, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation; (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, (i) becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities, and (ii) acquires the ability to appoint a majority of the board of directors, of such Party; or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its Affiliates' assets.

1.12 "Claim Date" shall mean the date on which any claim or assertion covered by Section 10.9 or any Claim covered by Section 14.1 is filed or threatened in writing.

1.13 "Clinical Supply Costs" shall mean, the Manufacturing Costs for Clinical Supply Requirements, [***].

1.14 "Clinical Supply Requirements" shall mean, with respect to a Co-Funding Product, (a) the quantities of such Co-Funding Product (or placebo or comparator agent, as the case may be) required by a Party or the Parties for Development in the Field under this Agreement in connection with the Global Development Plan and (b) quantities of the Co-Funding Product that are required by a Party for submission to a Regulatory Authority, including in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the world or in connection with any request by such Regulatory Authority.

1.15 "Co-Funding Percentage" shall mean, with respect to the Co-Funding Target and all Co-Funding Products, the [***] share of financial investment, expenses, costs, profit and loss as between the Parties on a world-wide basis [***].

1.16 "Co-Funding Product Invention" shall mean [***].

1.17 "Co-Funding Product" [See Annex 1.]

1.18 "Co-Funding Target" shall mean the Target that is the subject of the Exercised Option as set forth on Schedule 1.18.

1.19 "Combination Product" shall mean a Co-Funding Product incorporating or comprising at least [***] CP that is developed under this Agreement and at least [***].

1.20 "Commercialize" or "Commercialization" shall mean, with respect to a Co-Funding Product, the following activities undertaken or performed for such Co-Funding Product from and after the Option Exercise Date: [***].

1.21 "Commercially Reasonable Efforts" shall mean, with respect to the efforts to be expended by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, those reasonable, good faith efforts and resources to accomplish such objective, activity or decision consistent with those efforts and resources the relevant Party would normally use to accomplish a similar objective, activity or decision under similar circumstances, it being understood and agreed that with respect to the research, Development, Manufacture, seeking and obtaining Marketing Approval, or Commercialization of a product, such efforts and resources shall be consistent with the usual practices of such [***].

1.22 "Commercial Overhead Charge" shall mean, [***].

1.23 "Commercial Supply Costs" shall mean the Manufacturing Costs for Commercial Supply Requirements of the applicable Co-Funding Products. [***].

1.24 "Commercial Supply Requirements" shall mean, with respect to a Co-Funding Product, the quantities of such Co-Funding Product as are required to fulfill requirements for [***] in the world as approved by the JSC.

1.25 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2017, and each succeeding twelve (12) month period thereafter during the Term (except that the last Contract Year shall end on the effective date of any termination or expiration of the Term).

1.26 "Control" shall mean, with respect to any Material, Confidential Information, Intellectual Property right, or trademark that a Party (a) owns such Material, Confidential Information, Intellectual Property right, or trademark, or (b) has a license or right to use to such Material, Confidential Information, Intellectual Property right, or trademark, in each case of (a) or (b), with the ability to grant to the other Party access to, or a license or a sublicense (as applicable) of such rights to such Material, Confidential Information, Intellectual Property right, or trademark on the terms and conditions set forth herein, without (i) violating the terms of any agreement with any Third Party in existence as of the Effective Date or (ii) with respect to any such Material, Confidential Information, Intellectual Property right, or trademark that Intellia (or its Affiliate) in-licenses pursuant to an in-license agreement entered into by Intellia (or its Affiliate) with a Third Party after the Effective Date, having an obligation to pay any royalties or other consideration or being subject to additional conditions that are applicable to a sublicensee under such in-license, and with respect to a Regeneron Co-Funding Product unless included pursuant to the procedures set forth in Section 7.3, as applicable, or (iii) with respect to any such Material, Confidential Information, Intellectual Property Right, or trademark that Intellia (or its Affiliate) comes to own after the Effective Date that was invented [***] or (iv) with respect to any such Material, Confidential Information, Intellectual Property right, or trademark that Regeneron (or its Affiliate) in-licenses pursuant to an in-license agreement entered into by Regeneron (or its Affiliate) with a Third Party after the Effective Date, having an obligation to pay any royalties or other consideration or being subject to additional conditions that are applicable to a sublicensee under such in-license, and with respect to an Intellia Co-Funding Product unless Intellia agrees to assume the applicable obligations under such in-licenses, as applicable, or (v) with respect to any such Material, Confidential Information, Intellectual Property Right, or trademark that Regeneron (or its Affiliate) comes to own after the Effective Date, [***], in each of (i), (ii), (iii),(iv) and (v), as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, license or (sub)license; provided that, for clarity, Intellia will be deemed to Control such Intellectual Property as is licensed to it under the Intellia Existing Third Party Agreements (but subject to the terms and conditions of the Intellia Existing Third Party Agreements and with respect to Regeneron Co-Funding Products as and to the extent set forth in Section 7.3(e) and 10.12 of this Agreement with respect to such Intellia Existing Third Party Agreements). Notwithstanding anything in this Agreement to the contrary, in the event of a Change of Control of a Party, a Party will be deemed not to Control any Material, Confidential Information, Intellectual Property right, or trademark that are owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (other than such Party or

such Party's Affiliates immediately prior to the closing of such Change of Control) (y) prior to the closing of such Change of Control, except to the extent that any such Patent Rights, Know-How or Materials were Controlled by such Party or any of its Affiliates prior to such Change of Control, or (z) after such Change of Control to the extent that such Patent Rights, Know-How or Materials are invented or created by such Third Party or its Affiliates (other than such Party or such Party's Affiliates immediately prior to the closing of such Change of Control) after such Change of Control without using or incorporating any Patent Rights, Know-How or Materials licensed hereunder, provided that, notwithstanding the foregoing, following such Change of Control, such Party shall in all cases be deemed to Control all Patent Rights, Know-How and Materials (1) arising from the performance of activities under this Agreement or performance of activities under the Collaboration Agreement, including the Technology Collaboration, Regeneron Target Evaluation Programs, Intellia Target Evaluation Programs or Product R&D Programs on the terms as set forth in the Collaboration Agreement, or (2) that are improvements to, or derivatives of, or are otherwise based on or incorporates, any Patent Rights, Know-How or Materials Controlled by such Party or any of its Affiliates prior to such Change of Control or (3) that such Party or its Affiliates chooses to make available for the conduct of activities under this Agreement or actually uses in the conduct of activities under this Agreement.

1.27 "Converted CFP Inventions" [See Annex 1.]

1.28 "Co-Promote" or "Co-Promotion" shall mean the joint Detailing of Co-Funding Product(s) by the Parties (or their respective Affiliates) under the same trademark in the United States pursuant to the U.S. Co-Promotion Agreement.

1.29 "Country/Region Commercialization Budget" shall mean the budget(s) for a particular Contract Year developed by the Lead Party, reviewed by the JCC and JSC, and approved by the JSC for the applicable Country/Region Commercialization Plan.

1.30 "Country/Region Commercialization Plan" shall mean for a Co-Funding Product, [***]. The JCC shall propose and the JSC shall approve the number of Country/Region Commercialization Plans for each Co-Funding Product and the geographic scope of each such Plan.

1.31 "Cost of Goods Sold" shall mean, with respect to a given Quarter, the aggregate Manufacturing Costs (calculated in accordance with GAAP and Schedule 1.102) for all Co-Funding Products sold worldwide during such Quarter.

1.32 "CPI" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.33 "CPI Adjustment" shall mean the percentage increase or decrease, if any, in the CPI applicable to the applicable personnel for the [***] of the Contract Year prior to the Contract Year for which the adjustment is being made.

1.34 "CRISPR-Cas" and "CRISPR-Cas Materials" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.35 "CRISPR Product" or "CP" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.36 "Detail" shall mean, with respect to each Co-Funding Product, [***].

1.37 "Develop" or "Development" shall mean, with respect to a Co-Funding Product, the following activities undertaken or performed for such Co-Funding Product from and after the Option Exercise Date: [***]; and (b) any other research and development activities with respect to such Co-Funding Product, including, activities to [***].

1.38 "Development Costs" shall mean, with respect to a Co-Funding Product, those costs incurred by a Party for the Development of such Co-Funding Product in accordance with this Agreement and the applicable Global Development Plan [***] for the following items:

(a) Out-of-Pocket Costs [***] under this Agreement;

(b) Development FTE Costs;

(c) Clinical Supply Costs;

(d) Out-of-Pocket Costs incurred for [***];

(e) [***];

(f) Out-of-Pocket Costs and Development FTE Costs incurred pursuant to Section 3.7; and

(g) any other costs or expenses for such Co-Funding Product [***] or included as Development Costs under this Agreement.

[***]:

1. [***].
2. [***].
3. [***].
4. [***].

5. In no event shall a Party charge the other Party more than once for the same Development Costs under this Agreement, even if such costs are of benefit to multiple Co-Funding Products.

1.39 "Development Cost Forecast" shall mean the [***].

1.40 "Development FTE Cost" shall mean, for a given period, the number of FTEs for such period multiplied by the applicable Development FTE Rate.

1.41 "Development FTE Rate" shall mean (a) for each FTE based in the US, $[***] per FTE per Contract Year, adjusted each Contract Year on January 1 (commencing on January 1, 2019) in accordance with any CPI Adjustment, and (b) for each FTE based outside the U.S., such amount as the Parties shall agree to, in writing, in the local currency in the country where such FTE is based (which shall be converted into United States Dollars in accordance with Section 9.8). [***].

1.42 "Development Payment Report" on a Co-Funding Product-by-Co-Funding Product basis, shall mean the [***] report prepared by the Lead Party in accordance with Section 9.2 which sets forth in reasonable detail, for each Co-Funding Product individually (a) the Development Costs incurred by the Parties for such [***] and (b) the [***] Development True-Up calculated in accordance with Schedule 9.2.

1.43 "Directed to" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.44 "Exercised Option" [See Annex 1.]

1.45 "Executive Officers" shall mean the [***] of Regeneron and the [***] of Intellia, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.

1.46 "Ex-Vivo Field" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.47 "FCPA" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.48 "FDA" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.49 "Field" shall mean [***]; provided that, for clarity, the Field shall include [***]. The Field shall specifically [***].

1.50 "Field Force Cost" shall mean, for a given Co-Funding Product in the applicable country or Region, the product of (a) a percentage of the number of Lead Party's FTEs [***] and

(b) the applicable Field Force FTE Rate(s), in each case, with respect to such country or Region, as applicable. [***].

1.51 "Field Force FTE Rates" shall mean, on a country-by-country or Region-by-Region (as proposed by JCC and reviewed and approved by the JSC) basis (determined based on the location of the field force representative), a rate or rates proposed by the JCC and reviewed and approved by the JSC [***], as applicable, based upon the [***].

1.52 "Financial Dispute" shall mean any dispute related to [***].

1.53 "First Commercial Sale" shall mean, with respect to a given Co-Funding Product and a given country, the first commercial sale [***].

1.54 "FTE" shall mean a full time equivalent employee [***] employed by Party (or its Affiliate) who performs activities under a Plan, with such commitment of time and effort to constitute [***] employee performing such work on a full-time basis, which for purposes hereof shall be [***] per Contract Year (pro-rated for any Contract Year that is less than twelve (12) months).

1.55 "GAAP" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.56 "Gene" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.57 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year developed by the Lead Party, reviewed by the JCC and JSC, and approved by the JSC for the applicable Global Commercialization Plan.

1.58 "Global Commercialization Plan" shall mean, with respect to a Co-Funding Product, the [***], and approved by the JSC for the worldwide Commercialization of such Co-Funding Products in the Field and shall include the following:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***];

(h) [***]; and

(i) [***].

1.59 "Global Development Budget" shall mean the budget(s) for a particular Calendar Year [***] developed by the Lead Party, reviewed by the JDC and JSC, and approved by the JSC pursuant to Section 3.7(a) for the applicable Global Development Plan.

1.60 "Global Development Plan" shall mean, with respect to a Co-Funding Product, the [***], reviewed by the JDC and JSC, and approved by the JSC for the worldwide Development of such Co-Funding Product, which shall include the following:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***]; and

(f) [***].

1.61 "GLP Toxicology Study" shall mean a toxicology study, in a species that satisfies applicable requirements of a Regulatory Authority, using applicable Good Laboratory Practices ("GLP"), which meets the standard necessary for submission as part of an IND filing with the applicable Regulatory Authority.

1.62 "Good Practices" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.63 "Governmental Authority" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.64 "HSC" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.65 "ICH" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.66 "IND" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.67 "IND Acceptance" shall mean, with respect to a particular Co-Funding Product, that the particular IND for such Co-Funding Product was accepted by the FDA (or other applicable Regulatory Authority outside the United States if the IND was submitted to such Regulatory Authority outside the United States), as evidenced by no objection by the FDA (or such other applicable Regulatory Authority outside the United States) within [***].

1.68 "Initiation of GLP Toxicology Batch" shall mean, with respect to a particular Co-Funding Product, commencement of Manufacturing activities for an initial batch of Co-Funding Product intended to be used in a GLP Toxicology Study for such Co-Funding Product. For purposes of this paragraph, "commencement" means the start of any Manufacturing activities directly or via a Third Party manufacturer.

1.69 "Intellectual Property" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.70 "Intellia Background Patent Rights" shall mean those Patent Rights that (a) are Controlled by Intellia or any of its Affiliates (i) as of the Effective Date or (ii) during the Term [***], or (iii) during the IP Term, [***], or (iv) any (A) Patent Rights claiming priority to the Patent Rights, or (B) foreign equivalents of the Patent Rights, in each case of (A) and (B), in subclauses (i), (ii), or (iii), but in each of (i), (ii), (iii), and (iv) excluding Patent Rights to the extent within the [***], Intellia Materials Improvements, Intellia CRISPR-Cas IP, [***] Co-Funding Product Inventions (including Intellia Liver Product Inventions that become Co-Funding Product Inventions), Regeneron Materials Improvements, [***] and (b) are necessary or useful for the research, Development, Manufacturing, using, Commercialization, exploitation or selling of (i) a Co-Funding Product or (ii) CRISPR-Cas. The Intellia Background Patent Rights as of the Effective Date include those set forth on Schedule 1.47 of the Collaboration Agreement.

1.71 "Intellia Co-Funding Product" shall mean [***].

1.72 "Intellia Co-Funding Product Invention" shall mean a Co-Funding Product Invention that relates to or covers an Intellia Co-Funding Product.

1.73 "Intellia Co-Funding Target" shall mean with respect to an Intellia Co-Funding Product, [***].

1.74 "Intellia CRISPR-Cas IP" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.75 "Intellia Existing Third Party Agreements" shall mean the Caribou-Intellia License Agreement, including any amendments or restatements thereto as of the Effective Date or amendments following the Effective Date in accordance with Section 12.3, and the Invention Management Agreement under which Intellia is granted rights which are then sublicensed to Regeneron hereunder as Intellia Patent Rights, Intellia Know-How or Intellia Materials.

1.76 "Intellia Intellectual Property" shall mean the Intellia Patent Rights and the Intellia Know-How.

1.77 "Intellia Know-How" shall mean any and all Know-How that (a) is Controlled by Intellia or any of its Affiliates (i) as of the Effective Date or (ii) during the Term [***], and (b) is necessary or useful for the research, Development, Manufacturing, using Commercialization, exploitation or selling of (A) a Co-Funding Product or (B) CRISPR-Cas. Intellia Know-How shall include Know-How created during the Term in or related to Intellia Materials, Intellia Materials Improvements or Intellia CRISPR-Cas IP, Intellia Co-Funding Product Inventions as well as Intellia's interests in any [***].

1.78 "Intellia Liver Product" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.79 "Intellia Liver Product Invention" shall mean (a) all Intellectual Property that is invented by or on behalf of either Party (or by the Parties jointly) in the performance of Development, Manufacture or Commercialization of any Intellia Liver Product Directed to an Intellia Liver Target for which Regeneron exercised the Exercised Option and such invention is made prior to the Option Exercise Date, in each case that solely relates to or covers one or more Intellia Liver Products or components thereof (provided any such component is specific to such Intellia Liver Product), including (i) composition of matter or other chemical structure of such Intellia Liver Product(s), (ii) a method of making or using such Intellia Liver Product(s), or (iii) any gRNAs and crRNAs for one or more Intellia Liver Products, and (b) Patent Rights within any of the foregoing Intellectual Property. For clarity, an Intellia Liver Product Invention may constitute or comprise the combination of Intellia Materials and Regeneron Materials.

1.80 "Intellia Liver Target" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.81 "Intellia Materials" shall mean Intellia's (or its Affiliate's) proprietary [***] that are used in the performance of this Agreement or the Collaboration Agreement or otherwise licensed to Regeneron hereunder. [***].

1.82 "Intellia Materials Improvement" shall mean (a) any Intellectual Property that is invented by or on behalf of either Party (solely or jointly with the other) under this Agreement during the Term that constitutes or comprises an improvement, enhancement or other modification to any Intellia Materials [***] including any such Intellectual Property that comprises a composition of, or any method of using or making, Intellia Materials [***], (b) any Patent Rights to the extent within the Intellectual Property in the foregoing clause (a), in each case of (a) and (b) other than Co-Funding Product Inventions, Regeneron Materials Improvements, [***], Intellia CRISPR-Cas IP or [***] and (c) any Intellectual Property or Patents Rights that are covered by the definition of Intellia Materials Improvement in the Collaboration Agreement.

1.83 "Intellia Option" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.84 "Intellia Option Exercise Notice" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.85 "Intellia Patent Rights" shall mean the Intellia Background Patent Rights, Patent Rights to the extent within the Intellia Co-Funding Product Inventions and Intellia's interest in Patent Rights to the extent within the [***]. Intellia Patent Rights shall include the Patent Rights listed on Schedule 1.47 of the Collaboration Agreement as and to the extent pertaining to the Co-Funding Target and Co-Funding Products hereunder.

1.86 "Intellia Platform In-License" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.87 [***].

1.88 "Invention Management Agreement" shall mean that certain Consent to Assignments, Licensing and Common Ownership and Invention Management Agreement for a Programmable DNA Restriction Enzyme for Genome Editing, by and among Dr. Emmanuelle Charpentier, The Regents of the University of California, University of Vienna, CRISPR Therapeutics AG, ERS Genomics Ltd., TRACR Hematology Ltd., Caribou Biosciences, Inc. and Intellia dated December 15, 2016, including any amendments or restatements thereto as of the Effective Date or amendments following the Effective Date.

1.89 "IP Term" [See Annex 1.]

1.90 "Joint Improvement" shall mean, in each case of the following clauses (a) and (b) [***]:

(a) [***]; and

(b) [***].

1.91 "Joint Steering Committee" or "JSC" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.92 "Key Components" means, with respect to a Co-Funding Product: [***].

1.93 "Know-How" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.94 "Lead Party" [See Annex 1.]

1.95 "Legal Dispute" shall mean any dispute related to a Party's alleged material breach of this Agreement or the validity, breach, termination or interpretation of this Agreement, or Intellectual Property-related disputes.

1.96 "Liver Cell" shall have the meaning ascribed to such term in the Collaboration Agreement

1.97 "Liver Product" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.98 "Liver Target" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.99 "MAA Acceptance" shall mean, with respect to a particular Co-Funding Product, that the particular biologics application, new drug application, or its equivalent for such Co-Funding Product was accepted by the FDA (or other applicable Regulatory Authority outside the United States if the particular biologics application, new drug application, or its equivalent was submitted to such Regulatory Authority outside the United States).

1.100 "Major Market Country" shall mean any of the following: [***] and, with respect to any Co-Funding Product, [***].

1.101 "Manufacture" or "Manufacturing" shall mean activities directed to [***] Co-Funding Product [***], as the case may be.

1.102 "Manufacturing Cost" shall mean the fully burdened cost [***] of Manufacturing a Co-Funding Product [***].

1.103 "Manufacturing Plan" shall mean, with respect to a Co-Funding Product, the plan developed by the Lead Party, in consultation with the JMC, and reviewed and approved by the JSC as described in Section 8.6 for the Manufacture of such Co-Funding Product.

1.104 "Marketing Approval" shall mean all approvals of the applicable Regulatory Authority necessary for the marketing and sale of a Co-Funding Product in a given country (or other jurisdiction).

1.105 "Modulate" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.106 "Net Sales" shall mean, with respect to a Co-Funding Product, the gross amount invoiced for bona fide arms' length sales of all units of such Co-Funding Product in the Field by or on behalf of the Lead Party or its Affiliates or sublicensees (but excluding distributors) to the first Third Party (including distributors), less the following deductions, consistently applied:

(a) [***];

(b) [***];

(c) [***];

(d) [***];

(e) [***];

(f) [***];

(g) [***];

(h) [***];

(i) [***];

(j) [***]; and

(k) [***].

Such amounts will be determined from the books and records of a Lead Party, its Affiliates and sublicensees, maintained in accordance with GAAP. Net Sales in currency other than United States Dollars shall be converted into United States Dollars according to the provisions of Section 9.8 of this Agreement.

Sales between the Lead Party and its Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to and paid by Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Co-Funding Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated based [***].

Solely for purposes of calculating Net Sales, if the Lead Party or any of its Affiliates or sublicensees sells any Co-Funding Product in the form of a Combination Product, then [***].

1.107 "Non-Approval Trials" shall mean any surveys, registries and clinical trials, each of which are not intended to gain additional labeled indications.

1.108 [***].

1.109 [***].

1.110 "Option Exercise Date" shall mean, with respect to the Exercised Option, the date the Regeneron Option Exercise Notice or Intellia Option Exercise Notice, as applicable, is delivered to the other Party in accordance with Section 5.1(e)(i) or Section 5.2(c)(i) of the Collaboration Agreement, respectively.

1.111 "Option Package" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.112 "Other Co-Funding Agreement Inventions" shall mean (a) all Intellectual Property that is invented [***].

1.113 "Other Shared Expenses" shall mean, with respect to a Co-Funding Product, those costs and expenses incurred by a Party that are specifically referred to in Sections 5.4, 7.11, 8.4, 10.2(b), 10.3(c), 10.4(c), 10.5(b), 10.9, 10.10, and 14.1(c) and other costs agreed between the Parties to be included therein, to the extent that such costs and expenses do not include any costs and expenses included in Development Costs or Shared Commercial Expenses. [***].

1.114 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by Regeneron (or its Affiliate) or Intellia (or its Affiliate) [***].

1.115 "Participating Party" [See Annex 1.]

1.116 "Patent Application" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.117 "Patent Rights" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.118 "Patents" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.119 "Person" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.120 "Phase I Trial" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.121 "Phase II Trial" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.122 "Phase III Trial" shall mean a human clinical trial that would satisfy the requirements of 21 C.F.R. 312.21(c) (as amended or any replacement thereof), including, to the extent satisfying the foregoing requirements (a) a human clinical trial that becomes a registration trial sufficient for filing an application for a Marketing Approval for such product in the United States or (b) an equivalent clinical trial in conducted in a country other than the United States.

1.123 "Plan" shall mean any Country/Region Commercialization Plan, U.S. Commercialization Plan, Global Commercialization Plan, Global Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any Co-Funding Product under this Agreement.

1.124 "Pricing Approval" shall mean such [***].

1.125 "Product R&D Plan" shall mean a written plan and [***] budget associated with the discovery, research, pre-clinical Development, and Manufacture of a Regeneron Co-Funding Product as originally agreed to under the Collaboration Agreement (that was formerly referred to as a Regeneron Product under the Collaboration Agreement), which plans shall be incorporated and made a part of the Global Development Plan for the relevant Regeneron Co-Funding Product in accordance with Section 3.2.

1.126 "Product R&D Program" shall mean collectively, or individually, as applicable, the research and development program(s) to be performed under the Collaboration Agreement that was intended to discover, research, Manufacture and Develop Regeneron Co-Funding Products Directed to a Regeneron Target that is a Liver Target as originally agreed to under the Collaboration Agreement (that was formerly referred to as a Regeneron Product under the Collaboration Agreement), as set forth in the applicable Product R&D Plan(s) which program shall be incorporated and made a part of the Development for the relevant Regeneron Co-Funding Product in accordance with Section 3.2.

1.127 "Product Trademark" shall mean, with respect to each Co-Funding Product, the trademark(s) proposed by the Lead Party, reviewed by the JCC and JSC, and approved by the JSC for use on such Co-Funding Product throughout the world and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the Lead Party, reviewed by the JCC and JSC, and approved by the JSC.

1.128 "Profit Payment Report" shall mean a consolidated [***] report prepared by the Lead Party (based on information reported under Section 9.4) setting forth in reasonable detail, for each Major Market Country, and in the aggregate, worldwide as a whole, [***]. If an item is included in one [***] report, in no event shall the same item be included in a subsequent [***] Report.

1.129 "Promotional Materials" shall mean, with respect to each Co-Funding Product and country in which such Co-Funding Product is or will be sold, promotional, advertising, communication and educational materials relating to such Co-Funding Product for use in connection with the marketing, promotion and sale of such Co-Funding Product in such country, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.130 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first (1st) Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of this Agreement.

1.131 "Regeneron Co-Funding Product" shall mean (a)(i) with respect to the Regeneron Target that is the subject of the Exercised Option, the Regeneron Product developed under the

Collaboration Agreement that is Directed to such Regeneron Target or (ii) with respect to an Intellia Liver Target that is the subject of the Exercised Option under Section 5.1(e) of the Collaboration Agreement and for which Regeneron is designated as the Lead Party, [***].

1.132 "Regeneron Co-Funding Product Invention" shall mean [***].

1.133 "Regeneron Co-Funding Target" shall mean with respect to a Regeneron Co-Funding Product, [***].

1.134 "Regeneron Contributed IP" shall mean [***], that is Controlled by Regeneron or its Affiliate.

1.135 "Regeneron Contributed Technology" shall mean (a) technology that is covered under the definition of Regeneron Contributed Technology in the Collaboration Agreement and (b) technology Controlled by Regeneron or its Affiliates [***].

1.136 [***].

1.137 "Regeneron Material Relationship" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.138 "Regeneron Materials" shall mean Regeneron's (or its Affiliate's) proprietary [***], that are used in the performance of this Agreement or the Collaboration Agreement or otherwise included in the Regeneron Contributed Technology. [***].

1.139 "Regeneron Materials Improvement" shall mean (a) any Intellectual Property that is invented by or on behalf of either Party (solely or jointly with the other) under this Agreement during the Term that constitutes or comprises an improvement, enhancement or other modification to any Regeneron Materials [***], including any such Intellectual Property that comprises a composition of, or any method of using or making, Regeneron Materials [***], (b) any Patent Rights to the extent within the Intellectual Property in the foregoing clause (a), [***].

1.140 "Regeneron Mice" shall mean Regeneron's proprietary, genetically modified mice that are used in the performance of this Agreement or the Collaboration Agreement, and any progeny or derivatives thereof shall constitute Regeneron Materials Improvements.

1.141 "Regeneron Option" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.142 "Regeneron Option Exercise Notice" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.143 "Regeneron Product" shall mean have the meaning ascribed to such term in the Collaboration Agreement.

1.144 "Regeneron Product Inventions" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.145 [***].

1.146 "Regeneron Target" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.147 [***].

1.148 "Region" shall mean such [***] or more countries that are grouped together for purposes of Commercialization of a particular Co-Funding Product as determined by the JCC.

1.149 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking Approval, and shall include any IND or Marketing Approval application.

1.150 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under this Agreement or the development, manufacture, or commercialization of products.

1.151 "Regulatory Filings" shall mean regulatory applications, submissions, dossiers, notifications, registrations, Approvals, or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary in order to Develop, Manufacture or Commercialize a Co-Funding Product in a particular country or regulatory jurisdiction.

1.152 [***].

1.153 [***].

1.154 "Reserved Ex-Vivo Field" shall mean (a) modification of cells using CRISPR-Cas where such modification is conducted ex vivo for the purpose of [***], (b) modification of HSCs using CRISPR-Cas where such modification is conducted ex vivo for the purpose of [***], and (c) modification of cells using CRISPR-Cas for use in [***].

1.155 "Shared Commercial Expenses" shall mean the sum of the following items, in each case [***], including a U.S. Commercialization Plan, or Global Commercialization Plan, [***], and to the extent that such items do not include any costs included in Development Costs:

(a) [***];

(b) [***];

(c) Field Force Costs;

(d) Out-of-Pocket Costs related to [***];

(e) Out-of-Pocket Costs related to [***];

(f) Out-of-Pocket Costs [***];

(g) Commercial Overhead Charge;

(h) Out-of-Pocket Costs related to [***];

(i) [***]; and

(j) [***].

[***].

1.156 "Target" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.157 "Technology Collaboration Inventions" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.158 "Terminated Co-Funding Target" shall mean the Co-Funding Target for which this Agreement is terminated in accordance with Article 16.

1.159 "Terminated Co-Funding Products" shall mean all CPs that are Directed to a Terminated Co-Funding Target that were formerly Co-Funding Products.

1.160 "Third Party" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.161 "Third Party Collaboration Agreement" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.162 "Third Party License" shall mean any agreement between a Party and a Third Party pursuant to which such Third Party grants a license to such Party with respect to Intellectual Property of such Third Party that pertains to a Co-Funding Product, which shall include the Intellia Existing Third Party Agreements and New Intellia Platform Licenses.

1.163 "Third Party License Payment" shall mean any payment due to any Third Party under any Third Party License, including upfront payments, royalties, milestone payments and any other payments.

1.164 "UC Technology License" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.165 "United States" or "U.S." shall have the meaning ascribed to such term in the Collaboration Agreement.

1.166 "U.S. Commercialization Budget" shall mean the budget(s) for a particular Contract Year developed by the Lead Party, reviewed by the JCC and JSC, and approved by the JSC for the U.S. Commercialization Plan.

1.167 "U.S. Commercialization Plan" shall mean for a Co-Funding Product, the Country/Region Commercialization Plan for the United States developed by the Lead Party in consultation with the Participating Party, reviewed by the JCC and JSC, and approved by the JSC.

1.168 "U.S. Export Control Laws" shall have the meaning ascribed to such term in the Collaboration Agreement.

1.169 The remaining capitalized terms used in this Agreement shall have the meanings set forth in the following Sections of this Agreement:

Term	**Section Reference**
"Acquiring Party"	12.6(d)
"Agreement"	Preamble
"Alleged Party"	16.5(b)
"Alleging Party"	16.5(b)
"Breach Notice"	16.5(b)
"Caribou"	1.10
"Claim"	14.1(a)
"[***]"	9.3
"[***]"	4.11(a)
"Committees"	2.3(b)
"Competing Program"	12.6(d)
"Confidential Information"	13.1(a)
"Consultation Party"	10.2(d)(i)
"Covered Claim"	9.3(b)
"CRISPR-Cas Materials"	1.34
"Damages"	14.1(a)
"Disclosing Party"	13.1(a)
"Effective Date"	Preamble
"Election Notice"	16.14
"[***]"	12.6(c)
"Form of U.S. Co-Promotion Agreement"	4.11(c)
"Global Commercialization Budget(s)"	4.3(a)
"Global Development Budget(s)"	3.7(a)
"Healthcare Prescriber"	1.36
"Indemnified Party"	14.2(a)

Term	**Section Reference**
"Indemnifying Party"	14.2(a)
"Intellia"	Preamble
"Intellia Indemnitees"	14.1(b)
"JCC"	2.3(b)
"JDC"	2.3(b)
"JFC"	2.3(b)
"JMC"	2.3(b)
"Joint CRISPR-Cas Improvements"	1.90(b)
"Lead Litigation Party"	10.4(b)(v)
"Marketing Guidelines"	2.6(b)(iii)
"Materials"	7.7(a)
"New Intellia Platform License"	7.3(c)
"Non-Acquiring Party"	12.6(d)(i)
"Participating Party Commitment Level"	4.11(a)
"Party" and "Parties"	Preamble
"[***]"	4.3(c)
"[***]"	3.7(c)
"Product Infringement"	10.4(a)
"[***]"	Schedule 9.2
"Receiving Party"	13.1(a)
"Redacted Agreement"	13.5(d)
"Regeneron"	Preamble
"Regeneron Agreements"	12.2(b) (Sub-Annex 1(A))
"Regeneron Indemnitees"	14.1(a)
"Responsible Party"	10.2(d)(i)
"SEC"	13.5(d)
"Subject Claim"	9.3(b)
"Subject Litigation"	16.14
"Term"	16.1
"Third Party Acquisition"	12.6(d)
"[***]"	4.11(b)
"Working Group"	2.3(b)

ARTICLE 2
AGREEMENT OVERVIEW AND COLLABORATION GOVERNANCE

2.1 Lead Party and Participating Party. For purposes of and subject to the terms and conditions of this Agreement, the Lead Party with respect to the Co-Funding Target and all Co-Funding Products Directed to such Co-Funding Target shall have primary responsibility and decision-making authority with respect to the Development, Commercialization and Manufacturing thereof and shall have the rights and obligations allocated to it as more fully set

forth in this Agreement, and the Participating Party shall have the rights and obligations allocated to it as more fully set forth in this Agreement.

2.2 Modification of the Collaboration Agreement by this Agreement, Conflicts, Drafting Principles; Incorporation by Reference.

(a) As contemplated by Section 5.4 of the Collaboration Agreement, this Agreement supersedes the Collaboration Agreement solely with respect to the particular Co-Funding Target and Co-Funding Products, as applicable, that is the subject of this Agreement. In the event there is any conflict between the provisions of this Agreement and the provisions of the Collaboration Agreement as it relates to the Co-Funding Target or a Co-Funding Product, as applicable, this Agreement shall control. Any dispute as to whether there is a conflict between the provisions of this Agreement and the provisions of the Collaboration Agreement shall be resolved in accordance with Section 2.9 and if applicable, Section 17.1(c) of the Collaboration Agreement (which is incorporated into this Agreement in accordance with Section 17.1 of this Agreement).[2]

(b) [See Annex 1.]

There are instances where certain provisions of this Agreement are identical to those provisions in the Collaboration Agreement and for purposes of brevity this Agreement incorporates by reference the applicable terms of the Collaboration Agreement. In such cases, references to the term "Agreement" within such provisions incorporated by reference shall be deemed to refer to this Agreement, and unless otherwise expressly provided in this Agreement, each of the other defined terms referenced therein shall be deemed to refer to the corresponding defined term under this Agreement (e.g., Party, Term, Contract Year) and all references to the terms "development", "commercialization" and "manufacture" and conjugations thereof within such provisions incorporated by reference shall be deemed to refer to "Development", "Commercialization" and "Manufacture" and conjugations thereof respectively to the extent such terms refer to the Development, Commercialization and Manufacture of the Co-Funding Products contemplated herein (as context requires).

2.3 Committees/Management.

(a) Joint Steering Committee. The Parties have established a JSC pursuant to the Collaboration Agreement which shall also oversee the activities of the Parties under this Agreement.

(b) Committees. In addition to the JSC, the Parties agree to establish, for the purposes specified herein, a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other committees or sub-committees as the Parties deem appropriate. The other Committees shall be established by the JSC at the times determined appropriate by the JSC. It is understood that the Parties may wish to establish multiple Committees reporting to the JSC, JDC, JFC and JCC with responsibility for different Co-Funding Products. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each

[2] NTD: This paragraph will be included in each Co-Co Agreement, as appropriate.

Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines. The JDC, JCC, JFC, JMC and JSC, and any other committees the Parties establish pursuant to this Section 2.3, are the "Committees."

(c) Decision Making. Without limiting Section 2.9, the Committees shall have the right to determine matters that are within their scope (as set forth in Section 2.2(d) of the Collaboration Agreement or Sections 2.4-2.8) or are otherwise expressly allocated to such Committee as set forth in this Agreement. The JSC shall operate by consensus. The Parties shall cause their respective representatives on a Committee to use their good faith efforts to give due consideration to the perspective of each Party's representatives and to resolve all matters presented to them as expeditiously as possible. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote.

(d) Membership. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Intellia. Each Party may replace its Committee members upon written notice (which may be via email) to the other Party. For clarity, Section 2.2(a) of the Collaboration Agreement shall continue to apply to the JSC.

(e) Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than [***], commencing from and after the time such Committee is established as provided herein. All Committee meetings may be conducted by telephone, video-conference or in person as determined by the Co-Chairpersons; provided, however, that each Committee shall meet in person at least [***]. Unless otherwise agreed by the Parties, all in-person meetings of each Committee shall be held on an alternating basis between Regeneron's facilities and Intellia's facilities. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any Co-Funding Product (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least [***] Business Days' prior written notice (which may be via email), except that emergency meetings may be called with at least [***] Business Days' prior written notice (which may be via email). For clarity, Section 2.4(c) of the Collaboration Agreement shall apply to meetings of the JSC with respect to this Agreement, except that the JSC shall continue to meet at least [***], and more frequently as either Party may reasonably request, until the expiration or termination of the Term of this Agreement.

(f) Authority. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and each Committee shall have solely the powers expressly assigned to it (as set forth in Section 2.4 of the Collaboration Agreement or Section 2.4-2.8) or are otherwise expressly allocated to such Committee as set forth in this Agreement, and no

Committee, including the JSC, shall have any power to amend, modify or waive compliance with this Agreement.

2.4 Joint Steering Committee.

(a) Additional Purpose. In addition to and without limiting the responsibility of the JSC under the Collaboration Agreement, the JSC shall have overall responsibility for the oversight of the activities of the Parties under this Agreement with respect to Co-Funding Products. The JSC shall (i) review and approve the overall strategy for an integrated worldwide Development program for each Co-Funding Product, including the Manufacture of Co-Funding Products for use in activities under the Plans and for the Commercialization of Co-Funding Products worldwide; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans; and (iii) to oversee the Committees and resolve matters referred by the other Committees to the JSC for decision-making and approval as set forth in this Agreement or otherwise, and to resolve matters on which such Committees are unable to reach consensus on.

(b) Additional Specific Responsibilities. In addition to and without limiting the duties of the JSC under the Collaboration Agreement, the JSC shall:

(i) annually review and approve the Global Development Plan(s) (including reviewing and approving an updated Development Cost Forecast), Manufacturing Plan(s), Global Commercialization Plan(s) and Country/Region Commercialization Plan(s), including the U.S. Commercialization Plan(s), if any;

(ii) [***], review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans;

(iii) approve the Product Trademark;

(iv) discuss the prospective or planned incorporation of any Intellectual Property under a Third Party License that would trigger a Third Party License Payment in connection with the Development, Commercialization or Manufacture of a Co-Funding Product;

(v) review and discuss and agree to any proposal made by the Lead Party to license Development, Commercialization or Manufacturing rights for any Co-Funding Product to any Third Party [***];

(vi) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy and Plan issues;

(vii) establish sub-committees of the JSC, as the JSC deems appropriate;

(viii) [See Annex 1]; and

(ix) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

(c) Information Sharing. Each Party will share information with the JSC in a timely manner concerning the progress of the Plans and, in any event, at least [***] prior to each regular [***] meeting of the JSC, and in connection therewith, each Party will provide to the JSC a written report (in electronic form) summarizing in reasonable detail the material activities undertaken by such Party in connection with such Plans since such Party's most recent report.

2.5 Joint Development Committee.

(a) Composition and Purpose. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the worldwide Development of each Co-Funding Product; (ii) to review and review and annual update and present to the JSC for approval the Global Development Plan(s) (and related Global Development Budget(s)); and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the activities of the Parties with respect to Co-Funding Products as directed by the JSC. The JDC shall be composed of at least [***] of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) Specific Responsibilities. In particular, the JDC shall be responsible for:

(i) reviewing and advising the JSC on the overall global Development strategy for each Co-Funding Product developed by the Lead Party;

(ii) review and provide input on the draft Global Development Plan(s) and related Global Development Budget(s) (including the Development Cost Forecast) prepared by the Lead Party and the implementation thereof, as described in Sections 3.6 and 3.7, and submitting material decisions with respect thereto for final approval by the JSC;

(iii) review and provide input on [***];

(iv) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Co-Funding Products;

(v) discussing [***];

(vi) overseeing, and discussing the [***] in connection with the Co-Funding Products;

(vii) [***] for Co-Funding Products conducted under the Global Development Plan(s); and

(viii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.

2.6 Joint Commercialization Committee.

(a) Composition and Purpose. The purpose of the JCC shall be to develop and propose to the JSC the strategy for the global Commercialization of Co-Funding Products worldwide, to oversee the implementation of the Global Commercialization Plans. The JCC shall be composed of at least [***] of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

(b) JCC Responsibilities. In particular, the JCC shall be responsible for:

(i) reviewing and advising the JSC on the overall global Commercialization strategy for each Co-Funding Product;

(ii) review and provide input on the draft Global Commercialization Plan(s) and related Global Commercialization Budget(s) and Country/Region Commercialization Plan(s), and related Country/Region Commercialization Budget(s), including the U.S. Commercialization Plan(s) and U.S. Commercialization Budget(s), prepared by the Lead Party, as described in Sections 4.2 and 4.3 and submitting material decisions with respect thereto for final approval by the JSC and the implementation thereof; reviewing and validating latest annual budget estimates for the current calendar year compared to the Global Commercialization Budget and Country/Region Commercialization Budgets, including the U.S. Commercialization Budgets, and submitting material decisions with respect thereto for final approval by the JSC;

(iii) for each Co-Funding Product, [***];

(iv) review and provide input on [***];

(v) review and provide input on [***];

(vi) review and provide guidance on [***];

(vii) review and provide input on [***];

(viii) discussing the [***];

(ix) review and provide input on [***];

(x) review and provide input on [***];

(xi) [***];

(xii) review and provide input on [***];

(xiii) discussing a [***]; and

(xiv) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC.

2.7 Joint Finance Committee. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the profit and loss sharing relationship between the Parties with respect to Co-Product under this Agreement, and submitting material decisions with respect thereto for final approval by the JSC, including such specific responsibilities set forth in Sections 3.7(b), 4.3(c), 9.7, and 9.10 and such other responsibilities determined by the JSC or set forth in this Agreement. The JFC also shall respond to inquiries from the JDC, the JMC and the JCC, as needed.

2.8 Joint Manufacturing Committee. Working with the JSC, JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing Manufacturing activities, including reviewing the Manufacturing Plan prepared by the Lead Party and any updates thereto and referring the foregoing for approval by the JSC and overseeing the specific activities set forth in Sections 8.6 and 8.7 and such other Manufacturing related activities determined by the JSC or set forth in this Agreement, [***]. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions of both Parties or their Affiliates as appropriate.

2.9 [See Annex 1.]

2.10 Resolution of Committee Disputes.

(a) Committee Disputes other than the JSC. In the event there is a dispute at the level of the JDC, JFC, JMC or JCC, the Parties, through such Committee, will seek to resolve the dispute as promptly as possible, but no later than [***] after a Party has delivered to the other Party a written request to resolve the matter, and in the event that no resolution is reached at the JDC, JFC, JMC or JCC, as applicable, such matter shall be promptly referred to the JSC.

(b) JSC Disputes. Disputes at the JSC shall be resolved as follows:

(i) In the event that the JSC, after a period of [***] from the date a matter is submitted to it for decision (including if the Parties are unable to agree on a Plan (or amendment thereto), or any other matter that must be resolved by the JSC), is unable to make a decision due to a lack of required unanimity, either Party may require that the matter be submitted to the Executive Officers for a joint decision by providing written notice to the other Party formally requesting that the dispute be resolved by the Executive Officers and specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers.

(ii) If the dispute is referred to the Executive Officers, then the Executive Officers shall diligently and in good faith attempt to resolve the referred dispute within [***] after receiving such written notification or such longer period of time as the Executive Officers may agree in writing. All such referred disputes shall require a joint decision of both Parties' Executive Officers.

(iii) If the Executive Officers cannot resolve such dispute within such [***] or other agreed period, such dispute will be resolved as follows:

(A) [***];

(B) [***]; and

(C) [***];

(D) [***].

2.11 Alliance Management. Section 2.3 of the Collaboration Agreement is hereby incorporated by reference into this Agreement, applied *mutatis mutandis*, except that the Alliance Managers shall continue in their role until the expiration or termination of the Term of this Agreement.

ARTICLE 3
DEVELOPMENT ACTIVITIES FOR CO-FUNDING PRODUCTS

3.1 Development of Co-Funding Products. [See Annex 1.]

3.2 Existing Product R&D Programs and Associated Product R&D Plans. [See Annex 1.]

(a) [See Annex 1.]

(b) [See Annex 1.]

3.3 New Product R&D Programs and Associated Product R&D Plans. [See Annex 1.]

3.4 [See Annex 1.]

3.5 Transition of Patent Prosecution Responsibilities. [See Annex 1.]

3.6 Preparation, Updates and Approval of Global Development Plans.

(a) With respect to each Co-Funding Product, the Lead Party in consultation with the Participating Party shall prepare, and the JDC shall review and present a Global Development Plan for approval by the JSC, and the JSC shall approve a Global Development Plan for such Co-Funding Product, within

[***] after the Option Exercise Date. [***], the Lead Party shall Develop the Co-Funding Product in accordance with the development plan previously being used by the Party developing such Co-Funding Product prior to the Option Exercise Date. An updated Global Development Plan for each Co-Funding Product will be prepared by the Lead Party in consultation with the Participating Party, reviewed by the JDC and presented by the JDC for approval by the JSC, and reviewed and approved by the JSC, at least [***] prior to the end of each Contract Year. Each Global Development Plan will be reviewed and if necessary updated by the Lead Party (with such update reviewed by the JDC and JSC and approved by the JSC) not less frequently than once every [***].

(b) [See Annex 1.]

3.7 Global Development Budgets.

(a) Approval. Each Global Development Plan for a Co-Funding Product shall include a related Global Development Budget and each Global Development Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC. [***].

(b) Changes. If either Party reasonably anticipates that the costs of its conducting, or having a Third Party conduct, any activity included in a Global Development Budget will exceed the budgeted amount therefor, or if the costs of conducting such activity do exceed the amount set forth in the Global Development Budget, or if additional activities are required, such Party shall notify the JSC and request a change to the applicable Global Development Budget. The JSC shall in good faith consider all such reasonable requests to change the Global Development Budget.

(c) Budgets and Overages. Each Party shall use Commercially Reasonable Efforts to ensure that the actual costs associated with the performance of activities allocated to it in the Global Development Plan for a Co-Funding Product for a given Contract Year do not exceed [***] of the budgeted costs allocated to such Party for such Contract Year as set forth in the budget. [***].

3.8 [See Annex 1.]

ARTICLE 4
COMMERCIALIZATION OF CO-FUNDING PRODUCTS

4.1 Commercialization of Co-Funding Products. Subject to the terms of this Agreement, including Section 4.5, the Lead Party shall undertake Commercialization activities with respect to Co-Funding Products pursuant to the Global Commercialization Plans and such Commercialization activities shall be under the general direction and oversight of the JCC and JSC. Except as otherwise agreed to by the Parties or explicitly set forth in this Agreement, the JSC will assign responsibility for conducting all Commercialization activities for a Co-Funding Product to the Lead Party. The Lead Party shall use Commercially Reasonable Efforts to Commercialize Co-Funding Products in accordance with this Agreement and the applicable Plans, and each Party shall use Commercially Reasonable Efforts to carry out the

Commercialization activities assigned to it in Global Commercialization Plans and Country/Region Commercialization Plans, including the U.S. Commercialization Plans, in a timely manner, and in each case shall conduct all such activities in compliance with Applicable Laws. The Lead Party shall be responsible for handling collection and receivables and recording and booking sales in each country worldwide [***].

4.2 Preparation, Updates and Approval of Global Commercialization Plans. With respect to each Co-Funding Product, a Global Commercialization Plan shall be prepared by the Lead Party in consultation with the Participating Party, and the JCC shall review and present to the JSC for approval, and the JSC shall approve a Global Commercialization Plan [***].

4.3 Global Commercialization Budget.

(a) Approval. Each Global Commercialization Plan for a Co-Funding Product shall include a related Global Commercialization Budget (each individually, a "Global Commercialization Budget" and collectively, the "Global Commercialization Budgets") and each Global Commercialization Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Commercialization Plan of which such Global Commercialization Budget is a part in accordance with this Agreement. Amendments and updates to any Global Commercialization Budget shall not be effective without the approval of the JSC.

(b) Changes. If either Party reasonably anticipates that the costs of its conducting, or having a Third Party conduct, any activity included in a Global Commercialization Budget will exceed the budgeted amount therefor, or if the costs of conducting such activity do exceed the amount set forth in the Global Commercialization Budget, or if additional activities are required, such Party shall notify the JSC and request a change to the applicable Global Commercialization Budget. The JSC shall in good faith consider all such reasonable requests to change the Global Commercialization Budget.

(c) Budgets and Overages. Each Party shall use Commercially Reasonable Efforts to ensure that the actual costs associated with the performance of activities allocated to it in the Global Commercialization Plan for a Co-Funding Product for a given Contract Year do not exceed [***] of the budgeted costs allocated to such Party for such Contract Year as set forth in the budget. [***].

4.4 Country/Region Commercialization Plans. Each Country/Region Commercialization Plan, including each U.S. Commercialization Plan, and all updates and amendments thereto will be consistent with the Global Commercialization Plan. It is anticipated that each Country/Region Commercialization Plan for a Co-Funding Product, including each U.S. Commercialization Plan, will be prepared by the Lead Party for the Co-Funding Product in consultation with the Participating Party, reviewed by the JCC and JSC, and approved by the JSC, at least [***]. Such Country/Region Commercialization Plan, including such U.S. Commercialization Plan, for each subsequent Contract Year shall be updated by the Lead Party

in consultation with the JCC, reviewed by the JCC and JSC, and approved by the JSC, at least [***].

4.5 Commercialization Efforts; Sharing of Commercial Information.

(a) The Lead Party (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Co-Funding Products in the Field worldwide in accordance with the Global Commercialization Plans, the Marketing Guidelines and, as applicable, the Country/Region Commercialization Plan(s), including each U.S. Commercialization Plan. Without limiting the generality of the foregoing, [***] in accordance with Section 4.11, and subject to Section 4.11 (1) the Participating Party shall use Commercially Reasonable Efforts to perform the anticipated total Co-Promotion effort at the Participating Party Commitment Level, and (2) the Lead Party shall use Commercially Reasonable Efforts to perform the anticipated total Co-Promotion effort above the Participating Party Commitment Level, in each case, with respect to the Co-Funding Products in the Field in accordance with the approved U.S. Commercialization Plan, consistent with the Global Commercialization Plan and in accordance with all Applicable Laws.

(b) The Lead Party will provide the Participating Party with full access to material information directly relating to the Commercialization of each Co-Funding Product in the Field, [***]. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale (i) in each Major Market Country, the Lead Party will provide the Participating Party [***], with reports of the activity within its field force in each such Major Market Country and summarizing in reasonable detail other marketing and promotional activities undertaken by the Lead Party, and (ii) with respect to the U.S., if the Participating Party exercises its rights to Co-Promote a Co-Funding Product in accordance with Section 4.11, the Participating Party will provide the Lead Party, [***], with reports of the Participating Party's Co-Promotion activity within its field force in the United States, in each of (i) and (ii) which will include reasonable data from reports created by a Party for its internal management purposes.

4.6 Promotional Materials. The Lead Party will be responsible, [***], the Global Commercialization Plan and the Country/Region Commercialization Plans (as applicable), including the U.S. Commercialization Plans (as applicable), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the world. Without limiting Section 10.11, the JCC shall review and comment on [***].

4.7 Promotional Claims/Compliance. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any Co-Funding Product other than as permitted by Applicable Laws. When distributing information related to any Co-Funding Product or its use (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all Applicable Laws and any applicable guidelines established by the pharmaceutical industry in the applicable country.

4.8 [***].

4.9 Market Exclusivity Extensions. [***].

4.10 Post Marketing Approval Obligations. Subject to the provisions of this Agreement, the Lead Party shall comply with any post-Approval obligations with respect to a Marketing Approval with respect to any Co-Funding Product in any country, imposed by Applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

4.11 The Participating Party's Co-Promotion Option in the United States.

(a) Exercise of Co-Promote Option. Subject to this Section 4.11, with respect to the Co-Funding Target and all Co-Funding Products that are Directed to such Co-Funding Target, in the event the Participating Party desires to Co-Promote a Co-Funding Product in the United States, the Participating Party shall notify the Lead Party of its decision regarding whether to Co-Promote such Co-Funding Product in the United States no later than [***] (such notification, a "Co-Promotion Exercise Notice"). If the Participating Party does not timely deliver to the Lead Party a Co-Promotion Exercise Notice by the deadline set forth above, as applicable, the Participating Party's right to Co-Promote such Co-Funding Product in the United States shall immediately and permanently expire.

(i) Detailing and Co-Promotion FTE Efforts. The Participating Party shall specify in its Co-Promotion Exercise Notice the [***]. Notwithstanding the Participating Party's exercise of its option pursuant to Section 4.11, the Lead Party shall continue to be solely responsible for sales force training, unless agreed otherwise by the JSC.

(ii) In the event the Participating Party, either directly or through or its Affiliates, is not commercializing a product in the United States at the time of the Participating Party's election to Co-Promote a Co-Funding Product in accordance with this Section 4.11(a), the Participating Party may only exercise its election to Co-Promote such Co-Funding Product in the event the Participating Party has an existing sales force in the United States at the time of its election to Co-Promote such Co-Funding Product, [***]. On a Co-Funding Product by Co-Funding Product basis, any costs incurred by the Participating Party [***].

(iii) [***].

(b) Co-Promotion Agreement. [***].

(c) [***].

ARTICLE 5
CLINICAL AND REGULATORY AFFAIRS

5.1 Regulatory Coordination.

(a) Subject to the terms of this Agreement, the Lead Party shall determine the appropriate regulatory strategy with respect to Co-Funding Products, in consultation with the Participating Party under the general direction and oversight of the JDC, JCC, and JSC. The Lead Party shall consult with the Participating Party in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Co-Funding Products worldwide.

(b) Regulatory Filings.

(i) The Lead Party shall be responsible for submitting and maintaining all such Regulatory Filings and shall act as the point of contact for regulatory communications with each applicable Regulatory Authority with respect to each Co-Funding Product. The Lead Party (or its designee) shall own all such regulatory materials, including all INDs and Approvals with respect to Co-Funding Products. Without limiting the foregoing, the Lead Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each Co-Funding Product, subject to the oversight of the JSC. The Lead Party shall perform all such activities in accordance with the Plans and all Applicable Laws.

(ii) [See Annex 1.]

(c) [See Annex 1.]

(d) The Parties shall [***].

(e) The Lead Party shall provide the Participating Party as promptly as practicable with written notice and copies of any (i) draft and final Regulatory Filings or other filings with, (ii) submissions [***] to and (iii) material communications with, Regulatory Authorities pertaining to the Development and/or Commercialization of a Co-Funding Product under the Plans, and shall afford the Participating Party's representatives an opportunity to review the foregoing filings, submissions and correspondence (including all annual and periodic safety reports for Co-Funding Products), [***].

5.2 Labeling. For each Co-Funding Product, [***].

5.3 Regulatory Events. Each Party shall keep the other Party informed, as soon as possible but no later than the time period set forth below after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, which:

(a) raises any material concerns regarding the safety or efficacy of any Co-Funding Product, for which the time period for informing the other Party will be no later than [***]; or

(b) is reasonably likely to lead to a recall or market withdrawal of any Co-Funding Product anywhere in the world, for which the time period for informing the other Party will be no later than [***].

Information that shall be disclosed pursuant to this Section 5.3 shall include, the following matters with respect to Co-Funding Products:

(i) Governmental Authority inspections or audits of Manufacturing, Development, distribution or other facilities;

(ii) receipt of a complete response letter, refusal to file, warning letter or similar communications issued by a Regulatory Authority; and

(iii) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, enforcement action, seizure or injunction.

5.4 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Co-Funding Product shall be made by the Lead Party, and the Lead Party shall make any such decision, to the extent reasonably possible, in consultation with the Participating Party. In any event and without limiting the previous sentence, [***].

ARTICLE 6
LICENSES

6.1 Intellia License to Regeneron for Regeneron Co-Funding Products. With respect to Regeneron Co-Funding Products, Section 6.3 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), except all references to the IP Term shall be deemed to refer to the IP Term as defined in this Agreement. Notwithstanding the foregoing, Intellia reserves the rights under the licenses granted under this Section 6.1 to perform the activities designated to it under a Global Development Plan, Global Commercialization Plan, and U.S. Commercialization Plan, if applicable, and for the supply of Regeneron Co-Funding Products under Section 8.2.

6.2 Regeneron License to Intellia for Regeneron Co-Funding Products. Regeneron shall grant, and hereby grants, to Intellia a non-exclusive, worldwide license under the Regeneron Contributed IP solely to the extent necessary for Intellia to perform the activities designated to it under the applicable Global Development Plan, Global Commercialization Plan, and U.S. Commercialization Plan, if applicable, for such Regeneron Co-Funding Products and for the supply of such Regeneron Co-Funding Products under Section 8.2. Intellia may sublicense the license granted under this Section 6.2 only in accordance with Section 7.2(c) and only as necessary to enable permitted subcontractors to perform such activities in accordance with Section 7.2(b).

6.3 Regeneron License to Intellia for Intellia Co-Funding Products. Regeneron shall grant, and hereby grants, to Intellia a non-exclusive, worldwide, sublicensable in multiple tiers (in accordance with Section 7.2(c)) license under that portion of the Regeneron Contributed IP that Regeneron contributed in connection with Intellia Co-Funding Products, to develop, make, have made, use, sell, offer for sale, and import Intellia Co-Funding Products for use in the Field. [See Annex 1.]

6.4 Unblocking License. [See Annex 1.]

6.5 Intellia License to Regeneron for Intellia Co-Funding Products. Intellia shall grant, and hereby grants, to Regeneron a non-exclusive, worldwide license under the Intellia Intellectual Property solely to the extent necessary for Regeneron to perform the activities designated to it under the applicable Global Development Plan, Global Commercialization Plan, and U.S. Commercialization Plan, if applicable, for such Intellia Co-Funding Product. Regeneron may sublicense the license granted under this Section 6.5 only in accordance with Section 7.2(c) and only as necessary to enable permitted subcontractors to perform such activities in accordance with Section 7.2(b).

6.6 Mutual License to Materials. Each Party shall grant, and hereby grants, to the other Party a non-exclusive, worldwide license under that portion of the Materials provided pursuant to Section 7.7 for use in accordance with the relevant Plan.

6.7 Ex-Vivo Field. With respect to Regeneron Co-Funding Targets, Section 6.5 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

6.8 [***].

6.9 [***].

ARTICLE 7
PERFORMANCE AND PERFORMANCE STANDARDS

7.1 Licenses Generally; No Implied License. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights, materials or Confidential Information of the other Party (either expressly or by implication or estoppel). Except as expressly provided in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise. With respect to Co-Funding Products for which Regeneron is the Lead Party, the last sentence of Section 7.1 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

7.2 Performance Standards.

(a) Affiliates. Each Party may carry out its obligations, and exercise its rights, under this Agreement through its Affiliates, and in such case, the Party carrying out such activities, or exercising such rights, through its Affiliate absolutely, unconditionally and irrevocably guarantees to the other Party the performance by such Party's Affiliates in accordance with this Agreement, including performance of responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patent Rights and Know-How Controlled by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

(b) Subcontracts. Each Party may perform any of its obligations or exercise its rights under this Agreement through one or more subcontractors; provided that (i) [***]; (ii) the subcontracting Party remains responsible for the work allocated to, and payment to, such subcontractors it selects to the same extent it would if it had done such work itself and the non-subcontracting Party will have the right to proceed directly against the subcontracting Party without any obligation to first proceed against its subcontractor; (iii) [***]; and (iv) the subcontractor agrees in writing to assign all inventions and intellectual property developed in the course of performing any such work under this Agreement, to the Party retaining such subcontractor (or to the other Party if such inventions or intellectual property are to be assigned to such other Party as required under this Agreement) and upon request to sign any documents to confirm or perfect such assignment and to cooperate in the preparation and prosecution of any such inventions. [***]. To the extent any licenses are granted under any subcontract agreements, such agreements will be subject to Section 7.2(c).

(c) Sublicensees.

(i) To the extent a license is sublicensable pursuant to the applicable license grant hereunder, or is required in connection with a permitted subcontracting pursuant to Section 7.2(b), the applicable Party may enter into sublicenses under such licenses granted in this Agreement, but subject to compliance with this Section 7.2(c) and the other applicable terms and conditions set forth in this Agreement. Any such sublicense agreement must be in writing and shall require the sublicensee of a Party to comply with all applicable obligations of such Party that are relevant to the sublicense granted, including the confidentiality and non-use obligations set forth in Article 13. [***]. With respect to Co-Funding Products for which Regeneron is the Lead Party, the last sentence of Section 7.2(c)(i) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). The Lead Party shall promptly notify the Participating Party of the grant of each such sublicense.

(ii) (A) With respect to any and all Other Co-Funding Agreement Inventions and Joint Improvements or any other Intellectual Property that is invented and jointly owned by the Parties under this Agreement, subject to the terms and conditions of this Agreement, each Party shall have the right to grant (sub)licenses (through multiple tiers) thereto for any purposes without the need to seek consent from or account to the other Party (and, for clarity, neither Party shall be required to obtain the consent of the other Party with respect to such (sub)license anywhere in the world and, to the extent that such consent is required in any country in the world, such consent is hereby granted); provided, that, Regeneron shall only be permitted to grant a (sub)license with respect to the [***]. [See Annex 1.]

(B) Notwithstanding the foregoing Section 7.2(c)(ii)(A), nothing in this Section 7.2(c)(ii)(B) shall in any way restrict, limit or prohibit or be deemed to restrict, limit or prohibit either Party from soliciting, negotiating, facilitating, executing or undergoing a Change of Control.

7.3 Third Party Agreements.

(a) Intellia will be responsible for delivering all payments under the Intellia Existing Third Party Agreements to the applicable Third Party counterparty thereto. The amounts of such payments shall be borne by the Parties pursuant to Section 7.5.

(b) Following the Effective Date during the Term, Intellia or its Affiliates, in its sole discretion (but subject to Section 7.4), may enter into new agreements with Third Parties to license technologies or Intellectual Property from such Third Parties, including pursuant to any Third Party Collaboration Agreements (to the extent such technologies or Intellectual Property, as applicable, were not licensed by Intellia or any of its Affiliates as of the Effective Date) (an "Intellia Platform In-License").

(c) Commencing on the Effective Date and continuing until the expiration of the IP Term [***], if Intellia or its Affiliates enters into any Intellia Platform In-License during such period that may be useful or necessary in connection with the Development, Manufacture,

Commercialization or use of a Co-Funding Product, then Intellia will provide written notice of such license to the JSC, including a redacted copy of each such Intellia Platform In-License (which may be redacted for information not pertinent to this Agreement to the extent that such redactions do not reasonably impair the JSC's ability to evaluate whether it wants to include such Intellia Platform In-License as a New Intellia Platform License under this Agreement), so the JSC (subject to dispute resolution pursuant to Section 2.9) may elect whether to include such license under this Agreement [***].

(d) [See Annex 1.]

(e) [***].

7.4 Coordination of Third Party Intellectual Property Licensing.

(a) During the Term, if either Party (or its Affiliate) desires to obtain a license to Intellectual Property of a Third Party for use in connection with the Development, Commercialization or Manufacture of a Co-Funding Product (but not for any broader use), then prior to entering into such license, the JSC shall discuss in good faith and coordinate the licensing of such Intellectual Property. In the case of JSC approval [***].

(b) [See Annex 1.]

7.5 Third Party License Payments. Subject to [***], all Third Party License Payments made by a Party in accordance with Section 7.3, Section 7.4, Section 7.12 (if applicable) [***] shall be included in the Profit Split and shared by the Parties in accordance with their respective Co-Funding Percentages [***].

7.6 Records.

(a) Records.

(i) Section 7.5(a)(i) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and all references in such provisions to the Technology Collaboration and Technology Collaboration Plan shall be deemed to refer to this Agreement and to the applicable Plan, respectively.

(ii) [***].

(b) Record Keeping Generally. Section 7.5(b) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

7.7 Materials for Development Plans.

(a) Contributed Materials. To facilitate the conduct of activities hereunder, a Party shall provide the [***], collectively, "Materials"). Except as is set forth in the Product R&D Plan with respect to a Regeneron Co-Funding Product or a Party agrees to provide Materials to the other Party as set forth in a Plan, neither Party shall be obligated to provide any Materials to the other Party. Neither Party shall use the Materials of the other Party except in accordance with a Plan. All such Materials will remain the sole property of the providing Party. The receiving Party will (i) itself retain control of all such Materials, (ii) use such Materials only in the fulfillment of obligations or exercise of rights under this Agreement, (iii) not use such Materials or deliver the same to, or for the benefit of, any Third Party, without the providing Party's prior written consent [***] and (iv) not use such Materials in research or testing involving human subjects, without the providing Party's prior written [***]. The Materials supplied under this Section 7.7 are supplied "as is", and accordingly the receiving Party agrees to use prudence and appropriate caution in the use, handling, storage, transportation and disposition and containment of all such Materials, as not all of their characteristics may be known. [***].

(b) Regeneron Mice. Section 7.7(b) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

7.8 Debarment. Section 7.8 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

7.9 No Use of Non-Controlled IP in Performance of Activities under this Agreement. Each Party hereby covenants to the other Party that in the course of conducting its activities under this Agreement it will not use in or contribute in the performance of activities under this Agreement, any material, Confidential Information, Intellectual Property, or trademark that such contributing Party knows (without any duty to inquire) misappropriates the Intellectual Property of a Third Party. The Parties acknowledge and agree that this Section 7.9 is not intended to be, and shall not be deemed to be, a covenant against non-infringement of Intellectual Property.

7.10 Further Assurances and Transaction Approvals. Section 7.10 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

7.11 [See Annex 1.]

7.12 [See Annex 1.]

ARTICLE 8
CO-FUNDING PRODUCT MANUFACTURING

8.1 Non-GMP Manufacture of Co-Funding Products. [See Annex 1.]

8.2 Supply for Product R&D Program or its Equivalent. [See Annex 1.]

8.3 Supply Beyond Pre-Clinical.

(a) On or before the later to occur of (i) [***] for a Co-Funding Product or (ii) [***], the JMC shall discuss alternatives for the Manufacture and supply of Co-Funding Products beyond pre-clinical supply, including Initiation of GLP Toxicology Batch and GMP Manufacturing needed to support an IND, in each case, for a Co-Funding Product.

(b) [See Annex 1.]

8.4 [See Annex 1.]

8.5 Clinical and Commercial Supply. With respect to a Co-Funding Product, the Lead Party will be responsible for and will use Commercially Reasonable Efforts to adequately and timely Manufacture or have Manufactured the Clinical Supply Requirements and Commercial Supply Requirements of Co-Funding Products worldwide in accordance with the Manufacturing Plan and in accordance with Applicable Laws, including applicable Good Practices. The Lead Party will be responsible for and will use Commercially Reasonable Efforts to perform the filling, packaging, labeling and testing of the Clinical Supply Requirements and Commercial Supply Requirements for Co-Funding Products for use under this Agreement in accordance with Applicable Laws, including applicable Good Practices. The Parties through the JMC shall discuss in good faith the Manufacture of Co-Funding Products, and reasonably cooperate with each other in all such supply matters pertaining to the Co-Funding Products under this Article 8.

8.6 Manufacturing Plans. With respect to a Co-Funding Product, the Lead Party, in consultation with the JMC, will develop and update as necessary, for each Co-Funding Product, a Manufacturing Plan, which shall be reviewed and approved by the JSC. [***]. Each Manufacturing Plan shall set forth the [***]. The Manufacturing Plan (including each annual update thereto) for a Co-Funding Product shall be prepared by the Lead Party in consultation with the Participating Party, reviewed by the JMC, presented to the JSC for approval, and reviewed and approved by the JSC at least [***]. The Lead Party shall use Commercially Reasonable Efforts to perform its responsibilities in accordance with the approved Manufacturing Plans. Upon the Participating Party's written request, the Lead Party shall provide the Participating Party with complete and accurate copies of material Manufacturing-related records.

8.7 [***].

ARTICLE 9
PAYMENTS

9.1 Reimbursement for Past Expenses. [See Annex 1.]

9.2 Sharing of Profits and Development Costs from Co-Funding Products

. Commencing on the Effective Date and continuing during the Term, on a Co-Funding Product-by-Co-Funding Product basis, the Parties shall share Profits and Development Costs and other costs equally for all Co-Funding Products Directed to a Co-Funding Target as described in Schedule 9.2, subject to Section 9.3.

9.3 [***].

(a) [***].

(b) [***] have been paid and releases have been granted concerning such Covered Claims.

9.4 Periodic Reports. Intellia and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:

(a) Within [***] in which the First Commercial Sale of any Co-Funding Product occurs in any country in the world, the Lead Party shall deliver electronically to the Participating Party a monthly detailed Co-Funding Product Net Sales report, in each case with monthly and year-to-date sales in local currency and in each country in which such Co-Funding Product is sold, such reporting obligation to commence with the month in which the First Commercial Sale of any Co-Funding Product occurs in any country;

(b) Within [***], the Lead Party and the Participating Party shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party [***] in connection with each Global Development Plan, together with a statement of Development Costs incurred by such Party [***], which statement shall detail those amounts to be included in the Development Payment Report for such [***];

(c) Within [***] in which the First Commercial Sale of any Co-Funding Product occurs in any country in the world, the Lead Party shall deliver electronically to the Participating Party a written report setting forth, on a country-by-country basis for such [***], for each country, (i) the Co-Funding Product Net Sales of each Co-Funding Product in local currency and in United States Dollars, (ii) Co-Funding Product quantities sold and (iii) gross Co-Funding Product sales and an accounting of the deductions from gross sales permitted by the definition of Co-Funding Product Net Sales;

(d) Within [***], each Party that has incurred any Other Shared Expenses, Shared Commercial Expenses or Cost of Goods Sold in that [***] shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses, Shared Commercial Expenses and/or Cost of Goods Sold incurred by such Party in such [***] in the aggregate on a worldwide basis and also on a Major Market Country-by-Major Market Country basis and on a Co-Funding Product-by-Co-Funding Product basis, in local currency and in United States Dollars, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;

(e) Within [***], the Lead Party shall provide to the Participating Party, in electronic form, a Development Payment Report in respect of such [***], combining the information reported by each Party pursuant to this Section 9.4(b) and showing its calculations in accordance with Schedule 9.2 of the amount of any payments to be made by the Parties hereunder for such [***] as contemplated by this Section 9.4 [***] and, if applicable, providing for the netting of such payments; and

(f) Within [***], the Lead Party shall deliver electronically to the Participating Party a Profit Payment Report in respect of such [***], combining the information reported by each Party pursuant to this Section 9.4(c)-(d) and showing its calculations in accordance with Schedule 9.2 of the amount of any payments to be made by the Parties hereunder for such [***] as contemplated by this Section 9.4 [***] and, if applicable, providing for the netting of such payments.

9.5 Adjustments to FTE Rates. Notwithstanding anything herein to the contrary, upon the request of either Party, such request not to be delivered more than once per Contract Year, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Field Force FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.6 Funds Flow. The Parties shall make [***] Development True-Up and [***] Profit True-Up payments as set forth in Schedule 9.2. If the Lead Party is the Party owing [***] Development True-Up or [***] Profit True-Up payment(s) based on the calculations in the applicable Development Payment Report or Profit Payment Report, it shall, subject to Section 9.10, make such payment to the Participating Party within [***] after its delivery to the Participating Party of such Development Payment Report or Profit Payment Report, as applicable and receipt of an invoice therefor from the Participating Party. If the Participating Party is the Party owing the [***] Development True-Up or [***] Profit True-Up payment(s) based on the calculations in the applicable Development Payment Report or Profit Payment Report, it shall, subject to Section 9.10, make such payment to the Lead Party within [***] after its receipt of such Development Payment Report or Profit Payment Report, as applicable, from the Lead Party and receipt of an invoice therefor from the Lead Party. If agreed between the Parties, the Parties may also net the collective payment(s) due under the Development Payment Report and Profit Payment Report. In the event that the Third Party Licenses entered in compliance with this Agreement reasonably require the payment of royalties or other amounts payable thereunder (to the extent attributable to the Manufacture, Development and/or Commercialization of Co-Funding Products) on a schedule other than the schedule set forth in this Agreement for [***] Development True-Up or [***] Profit True-Up payment(s), the Parties shall discuss in good faith an appropriate schedule upon which the Party that is not party to such Third Party License shall make such payment to the other Party or its designee, and the Parties shall adjust the amounts payable for the next [***] Development True-Up or [***] Profit True-Up payment(s) accordingly to credit such paying Party for its pre-payment of any amounts under the Third Party Licenses.

9.7 Invoices and Documentation. The JFC shall propose and the JSC shall approve the form of any necessary documentation relating to any Development Costs or Profit Split payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder. Unless otherwise agreed by the JSC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.8 Payment Method and Currency. Section 9.9 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

9.9 Taxes. Section 9.10 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

9.10 Resolution of Payment Disputes. In the event there is a dispute relating to any payment obligations or reports hereunder, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. If the JFC is unable to resolve such payment dispute within such period then the matter shall be referred to the JSC. The Parties agree that if there is a dispute regarding any payment amount, only the disputed amount shall be withheld from the payment, and the undisputed amount shall be paid within the applicable timeframes.

9.11 Late Fee. Section 9.12 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

9.12 Effect of Intellia Option Exercise. If a Co-Funding Product constitutes a Regeneron Co-Funding Product, then no milestone payments or royalties shall be due or payable from Regeneron to Intellia under Article 9 of the Collaboration Agreement with respect to such Regeneron Co-Funding Product [***]. For clarity, Third Party License Payments (including pursuant to the Intellia Existing Third Party Agreements) shall be included in the Profit Split and shared by the Parties in accordance with their respective Co-Funding Percentages subject to the other terms and conditions of this Agreement that relate to their inclusion and allocation thereof.

9.13 [See Annex 1.]

9.14 [See Annex 1.]

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Newly Created Intellectual Property.

(a) Ownership of Newly Created Intellectual Property. Inventorship of Intellectual Property invented through the performance of activities under this Agreement shall be

determined in accordance with United States patent laws (regardless of where the applicable activities occurred) and ownership of such Intellectual Property shall follow inventorship. Notwithstanding the previous sentence, all right, title and interest in any [***], Regeneron Materials Improvements, Intellia Materials Improvements, Co-Funding Product Inventions and [***], in each case, shall be determined in accordance with the following terms and conditions:

(i) the Parties shall jointly own all [***];

(ii) Intellia shall solely own all Intellia Materials Improvements and Intellia Co-Funding Product Inventions [***]; and

(iii) Regeneron shall solely own all Regeneron Materials Improvements and Regeneron Co-Funding Product Inventions [***].

(b) [***].

(c) Treatment. All Intellia Materials Improvements shall be treated as Intellia Patent Rights or Intellia Know-How, as applicable, for purposes of this Article 10. All Regeneron Materials Improvements shall be treated as Regeneron Co-Funding Product Inventions for purposes of this Article 10.

(d) Invention Assignment; Assistance. Section 10.1(d) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(e) Joint Ownership of [***]. The Parties shall each own an equal, undivided interest in, and, subject to the other applicable provisions of this Agreement [***], each Party shall otherwise enjoy an equal undivided right to exploit any and all [***] including the right to use, practice and otherwise exploit for research, development, manufacturing, commercialization and other purposes (including to grant licenses or other similar rights under) the [***], without the need to seek consent from or account to the other Party (and, for clarity, neither Party shall be required to obtain the consent of the other Party with respect to the exploitation thereof anywhere in the world and, to the extent that such consent is required in any country in the world, such consent is hereby granted). The foregoing joint ownership rights shall not be construed as granting, conveying or creating any license or other rights to any of the other Party's other intellectual property, unless otherwise expressly set forth in this Agreement. Subject to any licenses granted under this Agreement and subject to the other applicable provisions of this Agreement [***] each Party shall grant and hereby grants its consent to the other Party to exploit, (sub)license, assign [***] where such consent is required under Applicable Law, and further shall confirm the foregoing in writing at the other Party's reasonable request. [***].

(f) Other Intellectual Property. Section 10.1(f) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(g) Employees and Consultants. Section 10.1(g) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(h) Disclosure. Each Party shall promptly disclose to the other Party all Intellectual Property that (i) is invented by such Party, its employees, agents and consultants pursuant to this Agreement and (ii) that is [***].

10.2 Prosecution and Maintenance of Patent Rights.

(a) Intellia Patent Rights. Intellia shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain the Intellia Patent Rights [***] (and as between the Parties, in the name of Intellia). Intellia shall be solely responsible for all fees and costs incurred for the preparation, filing, prosecution and maintenance of such Intellia Patent Rights, [***].

(b) [***]. Intellia shall, through counsel it selects and, for Major Market Countries, who has been approved by Regeneron (such approval not be unreasonably withheld, conditioned or delayed), use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications within [***], all such Patents and Patent Applications shall be in the name of Intellia and for [***], all such Patents and Patent Applications shall be jointly in the names of both Intellia and Regeneron and Intellia shall bear the costs thereof, [***]. For clarity, subject to Section 10.2(e), Regeneron shall not prepare, file, prosecute or maintain Patents or Patent Applications that contain any claims that claim only Intellia Co-Funding Product Inventions.

(c) Regeneron Co-Funding Product Inventions. Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications within Regeneron Co-Funding Product Inventions. All such Patents and Patent Applications shall be in the name of Regeneron [***]. For clarity, subject to Section 10.2(e), Intellia shall not prepare, file, prosecute or maintain Patents or Patent Applications that contain any claims that claim only Regeneron Co-Funding Product Inventions.

(d) Consultation Rights.

(i) Each Party shall confer with and keep the other Party reasonably informed regarding the status of such Party's activities under Section 10.2(a), 10.2(b) or 10.2(c), as applicable (the Party with primary responsibility under each such Section, the "Responsible Party", and the other Party, the "Consultation Party"). The Responsible Party shall have the following obligations with respect to the filing, prosecution and maintenance thereof [***], as applicable, including any action that would materially affect the scope or validity of rights under any Patent Applications or Patents (such as substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country) and the Responsible Party shall consider in good faith and discuss all reasonable comments thereto from the Consultation Party.

(ii) If either Party desires to file a patent application that discloses the Confidential Information of the other Party (including Confidential Information that is treated by this Agreement as the Confidential Information of both Parties), within a reasonable period of time prior to the anticipated filing date, a notice that specifies the Confidential Information to be disclosed within such patent application shall be provided to the other Party and, upon the request of the other Party, the filing Party shall be obliged at the other Party's discretion to either (A) remove the Confidential Information belonging solely to the other Party [***] from such patent application or (B) provide the other Party reasonably sufficient time [***] to file a Patent Application claiming or otherwise covering such Confidential Information (including Confidential Information that is treated by this Agreement as the Confidential Information of both Parties), as applicable (unless any disclosure resulting from such filing under this clause (B) is prohibited by any Third Party obligations of such other Party, in which case this clause (B) shall not be available and only clause (A) shall apply). Confidential Information of Regeneron includes the Regeneron Materials unless subject to the exceptions set forth in Section 13.2. Confidential Information of Intellia includes the Intellia Materials unless subject to the exceptions set forth in Section 13.2.

(e) Step-In Rights.

(i) [***].

(ii) [***].

(iii) [***].

(iv) [***].

(v) [***].

(f) Regeneron Contributed IP. As between the Parties, Regeneron shall have the sole and exclusive right, in its discretion and at its expense, to prepare, file, prosecute and maintain Patents and Patent Applications within the Regeneron Contributed IP and Intellia shall have no right to do so. For clarity, any such costs and expenses shall be borne solely by Regeneron and shall not be subject to sharing by the Parties in accordance with their respective Co-Funding Percentages and shall not be treated as Other Shared Expenses.

(g) Cooperation. Section 10.2(g) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(h) Cooperative Research and Technology Enhancement Act. Section 10.2(h) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

10.3 Administrative Patent Proceedings.

(a) Proceedings. Each Party will notify the other within [***] after receipt by such Party of information concerning the request for, or filing or declaration of, any reissue, post-

grant review, *inter partes* review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to [***].

(b) Product Infringement. If any proceeding under Section 10.3(a) involves Patents or Patent Applications involved in a Product Infringement under Section 10.4, then notwithstanding the provisions of Section 10.3(a), any decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, shall be made by the Party controlling such Product Infringement action pursuant to Section 10.4 in consultation with the other Party [***].

(c) Cost. All Out-of-Pocket Costs incurred in connection with any proceeding under Section 10.3(a) shall be borne solely by [***].

(d) Regeneron Contributed IP and Regeneron Materials Improvements. As between the Parties, Regeneron shall have the sole and exclusive right, in its discretion and at its expense, to handle any reissue, post-grant review, *inter partes* review, derivation proceeding, supplemental examination, interference, opposition, reexamination or other administrative proceeding relating to (i) Patents and Patent Applications within the Regeneron Contributed IP and (ii) Patents and Patent Applications claiming or otherwise covering Regeneron Materials Improvements. For clarity, any such costs and expenses shall be borne solely by Regeneron and shall not be subject to sharing by the Parties in accordance with their respective Co-Funding Percentages and shall not be treated as Other Shared Expenses.

10.4 Third Party Infringement Suits.

(a) Product Infringement. In the event that either Party or any of its Affiliates becomes aware of an actual, anticipated, or suspected infringement or misappropriation by a Third Party of (i) [***], or (ii) [***] (collectively (i) and (ii), "Product Infringement"), the Party that became aware of the Product Infringement shall promptly notify the other Party in writing of this actual or suspected infringement and shall provide such other Party with all available evidence in such Party's possession (and that is not subject to a binding contractual confidentiality obligation to a Third Party) supporting such actual or suspected infringement.

(b) Lead Litigation Party. The Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action with respect to any Product Infringement; provided, that:

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***]; and

(v) [***].

The Party initiating the litigations shall be referred to as the "Lead Litigation Party". The Lead Litigation Party cannot require the non-Lead Litigation Party to join in the suit, provided, however that [***].

(c) Costs. All Out-of-Pocket Costs incurred in the connection with the enforcement of a Product Infringement shall be borne [***] that is not the Lead Litigation Party.

(d) Recoveries. The amount of any recovery from any Product Infringement suit shall first be used to pay each of the Party's reasonable costs, including attorneys' fees, relating to such legal proceedings and the balance of any such recovery shall be retained by the Lead Litigation Party; provided, however, that with respect to any amounts of such recovery from any such Product Infringement suit (other than those amounts used to pay a Party's reasonable costs) that have been awarded (as reimbursement for lost sales or lost royalties) of Co-Funding Products, regardless of which Party is the Lead Litigation Party, such amounts shall be included in the calculation of Profit Split in accordance with Section 9.2.

(e) Assistance. In the event either Party initiates a proceeding pursuant to this Section 10.4, without any effect as to who is the Lead Litigation Party pursuant to the terms of Section 10.4(b), the other Party shall provide all assistance reasonably requested by the Lead Litigation Party [***].

(f) Settlements; Admissions. Section 10.4(f) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(g) Step-In Rights. Section 10.4(g) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(h) Biosimilar Applications. Section 10.4(h) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(i) Regeneron Contributed IP and Regeneron Materials Improvements. As between the Parties, Regeneron shall have the sole and exclusive right, in its discretion and at its expense, to handle enforcement relating to the Regeneron Contributed IP and Regeneron Materials Improvements.

10.5 BPCIA and Biosimilar Applications.

(a) BPCIA Listings.

(i) With respect to Regeneron Co-Funding Products, Regeneron will have sole decision-making authority with respect to the determination of which Intellia Patent Rights or Patent Rights Controlled by Regeneron or its Affiliates to submit to a Third Party that files a Biosimilar Application, or any other act of patent information exchange or listing as required by the BPCIA or other similar measure in any other country worldwide (provided that with respect

to Intellia Background Patent Rights, if such Patent Rights cover one or more products of Intellia or its (sub)licensees, then any such determination shall discussed in good faith by the Parties with respect to such Patent Rights); provided, that to the extent permitted by Applicable Law, Regeneron shall confer in good faith with Intellia regarding which, if any, such Intellia Patent Rights are listed pursuant to 42 U.S.C. § 262(l)(3)(A) (or any successor legislation) (or other similar measure in any other country worldwide), or otherwise included in any litigation with such a Third Party applicant.

(ii) With respect to Intellia Co-Funding Products, Intellia will have sole decision-making authority with respect to the determination of which Intellia Patent Rights to submit to a Third Party that files a Biosimilar Application, or any other act of patent information exchange or listing as required by the BPCIA or other similar measure in any other country worldwide; provided, that to the extent permitted by Applicable Law, Intellia shall confer in good faith with Regeneron regarding which, if any, such Intellia Patent Rights are listed pursuant to 42 U.S.C. § 262(l)(3)(A) (or any successor legislation) (or other similar measure in any other country worldwide), or otherwise included in any litigation with such a Third Party applicant.

(b) Biosimilar Applications. Notwithstanding anything to the contrary herein, if either Party receives a copy of a Biosimilar Application referencing a Co-Funding Product or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for marketing approval (such as in an instance described in 42 U.S.C. §262(l)(9)(C)), such Party shall within [***] notify the other Party. The owner of the relevant Patent Rights shall then seek permission to view the application and related confidential information from the filer of the Biosimilar Application if necessary under 42 U.S.C. §262(l)(1)(B)(iii). If either Party receives any equivalent or similar communication or notice in the United States or any other jurisdiction, either Party shall within [***] notify and provide the other Party copies of such communication to the extent permitted by Applicable Laws. Promptly after receiving notice of a Biosimilar Application referencing a Co-Funding Product or any equivalent or similar communication or notice in the United States or any other jurisdiction referencing a Co-Funding Product, the Parties shall enter into an appropriate joint defense agreement. Regeneron shall have the right to be the Lead Litigation Party with respect to a Regeneron Co-Funding Product and Intellia shall have the right to be the Lead Litigation Party with respect to an Intellia Co-Funding Product. A Party that is not the Lead Litigation Party in a litigation shall consent to being joined in a litigation or being named as the plaintiff in a litigation if such being joined or named as a plaintiff is necessary to confer standing to bring the litigation or is otherwise necessary for the pendency of the litigation, and in such instance the joined Party shall provide reasonable cooperation and assistance to the Lead Litigation Party, and all Out-of-Pocket Costs incurred by the joined Party in connection therewith shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses.

(c) Coordination. With regard to issues related to potential Biosimilar Applications referencing a Co-Funding Product, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

10.6 Extensions and Other Protections. The Lead Party shall have the sole right to apply for supplementary protection certificates, patent term extensions, patent term restorations or any other exclusivity, including as may be available under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (or comparable laws outside the United States of America), in respect of a Co-Funding Product. At the Lead Party's reasonable request, the other Party will provide reasonable assistance to the Lead Party in connection with any such applications. [***].

10.7 Patent Marking. Each Party shall comply with the patent marking statutes in each country in which a Co-Funding Product or Terminated Co-Funding Products, as applicable, is made, offered for sale, sold or imported by such Party, its Affiliates or sublicensees.

10.8 Third Party Claims Related to [***]. If either Party or its Affiliates shall learn of a Third Party claim, assertion or certification that the activities under this Agreement infringe or otherwise violate the intellectual property rights of any Third Party, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall [***].

10.9 Infringement of Third Party Patent Rights or Third Party Know-How. If any Co-Funding Product manufactured, used or sold by a Party, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right or misappropriation of Know-How, the Party first having notice of the claim or assertion shall promptly notify the other Party. Regeneron shall have the sole right, but not the obligation, to defend any such Third Party claim or assertion of infringement of a Regeneron Co-Funding Product. Intellia shall have the sole right, but not the obligation, to defend any such Third Party claim or assertion of infringement of an Intellia Co-Funding Product. The non-defending Party shall provide reasonable cooperation and assistance to the defending Party. Subject to Section 14.1, all Out-of-Pocket Costs incurred by the defending Party in connection with a defense against a Third Party claim or assertion pursuant to this Section 10.9 and by the non-defending Party in connection with providing the assistance set forth in the previous sentence [***].

10.10 Product Trademarks. The Lead Party shall exclusively own and be responsible for, filing, prosecuting, protecting and maintaining the Product Trademarks, including all enforcement and defense thereof. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance, enforcement and defense of Product Trademarks pursuant to this Section 10.10 shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses. The Participating Party shall provide all assistance reasonably requested by the Lead Party in connection with the maintenance, enforcement and defense of the Product Trademarks.

10.11 Use of Corporate Names. The Lead Party shall use Commercially Reasonable Efforts to include the Participating Party's name with [***] on materials related to the Product (including package inserts, packaging, trade packaging, internet pages, social media, samples and all Promotional Materials used or distributed in connection with the Product), unless to do so

would be prohibited under Applicable Law; provided, in the case of multi-product materials that refer to the Product as well as other (bio)pharmaceutical products [***]. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use [***].

10.12 Third Party Rights.

(a) Notwithstanding the foregoing provisions of this Article 10, the Parties acknowledge and agree that each Party's rights and obligations with respect to any Patent Rights under this Article 10 will be subject to the terms and conditions of [***].

(b) [See Annex 1.]

(c) This Section 10.12 shall not apply to, and expressly excludes, the Patent Rights licensed under any Third Party Collaboration Agreement.

ARTICLE 11
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

11.1 Books and Records. Section 11.1 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). Each Party shall keep its books of record and account to the extent related to this Agreement in a readily available and organized form to allow an independent auditor to verify the accuracy of all financial, accounting and numerical information provided in a reasonably efficient manner. To the extent an audited Party is reasonably determined to not be in compliance with the previous sentence, such audited Party shall be responsible for any additional fees charged by the independent auditor to the auditing Party as a result of additional time spent by the independent auditor assembling or organizing such information.

11.2 Audits and Adjustments. Section 11.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

11.3 GAAP. Section 11.3 of the Collaboration Agreement is hereby incorporated by reference into this Agreement

ARTICLE 12
REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 Joint Representations and Warranties. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized, validly existing, and in good standing under the laws of its jurisdiction of incorporation; (b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action necessary to enter into, deliver, and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of Applicable Laws; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to Applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting the licenses expressly to the other Party hereunder; (f) no broker, finder or investment banker is entitled to any brokerage, finder's

or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf; and (g) it has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement.

12.2 Additional Representations and Warranties of the Parties.

(a) By Intellia. [See Annex 1.]

(b) By Regeneron. [See Annex 1.]

12.3 Covenants.

(a) Each Party hereby covenants to the other Party as follows: (i) it will not during the Term grant any right or license to any Third Party which would be in conflict with the rights granted to the other Party under this Agreement, and (ii) neither Party will use the Patent Rights, Know-How, materials, or Confidential Information of the other Party outside the scope of the licenses and rights granted to it under this Agreement.

(b) Intellia (on behalf of itself and its Affiliates) hereby further covenants to Regeneron that it (and they) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) any rights to any Intellia Know-How or Intellia Patent Rights, in any manner that would conflict with, or would adversely interfere with, the grant of the rights or licenses granted to Regeneron hereunder.

(c) Regeneron (on behalf of itself and its Affiliates) hereby further covenants to Intellia that it (and they) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) any rights to any Regeneron Know-How or Regeneron Patent Rights, in any manner that would conflict with, or would adversely interfere with, the grant of the rights or licenses granted to Intellia hereunder.

(d) [See Annex 1.]

12.4 Compliance with Laws. Section 12.5 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

12.5 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY AND EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF ANY ACTIVITIES PERFORMED UNDER ANY PLAN OR THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY CO-FUNDING PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF NON-INFRINGEMENT, MERCHANTABILITY

AND FITNESS FOR A PARTICULAR PURPOSE.

12.6 Exclusivity. The Parties hereby agree as follows:

(a) Exception to Intellia Liver Exclusivity. For clarity, nothing in Section 12.7(a) of the Collaboration Agreement shall restrict or limit or otherwise be deemed to restrict or limit Intellia's rights under this Agreement to research, develop, manufacture, commercialize or otherwise exploit Intellia Co-Funding Products as a Lead Party in accordance with this Agreement or Intellia's rights under this Agreement to act as a Participating Party with respect to Regeneron Co-Funding Products.

(b) Target Exclusivity. [***].

(c) Change of Control of a Party. [***].

(d) Other Acquisitions by a Party. Notwithstanding Section 12.6(b), in the event that a Party or its Affiliates acquire a Third Party or a portion of the business of a Third Party (whether by merger, stock purchase, purchase of assets or other means of acquiring ownership) (such Party, the "Acquiring Party" and such acquisition, a "Third Party Acquisition") that is, immediately prior to such acquisition, conducting a research, development or commercialization program that, if conducted by such Party at such time, would be a breach of such Party's exclusivity obligation in Section 12.6(b) (a "Competing Program"), the Acquiring Party shall give the other Party express written notice thereof within [***] after the closing of such Third Party Acquisition and furthermore the Acquiring Party shall [***] after the closing of such Third Party Acquisition:

(i) [***];

(ii) [***]; or

(iii) [***].

(iv) [***].

ARTICLE 13
CONFIDENTIALITY

13.1 Confidential Information.

(a) Each Party and its Affiliates (in such capacity, collectively, the "Receiving Party") shall keep confidential, and other than as provided herein, shall not disclose, directly or indirectly, any proprietary or confidential information, including any proprietary data, inventions, documents, ideas, information, discoveries, or materials, Controlled by the other Party or its Affiliates (in such capacity, collectively, the "Disclosing Party"), whether in tangible or intangible form, including Regeneron Contributed IP and Intellia Know-How, that is disclosed pursuant to this Agreement (the "Confidential Information").

(b) Each Party and its Affiliates shall use the Confidential Information of the other Party and its Affiliates solely for the purpose of exercising its rights and performing its obligations hereunder.

(c) Each Party covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except (i) to its directors, officers, employees, agents, consultants and subcontractors to the extent necessary to perform such Party's obligations, or exercise such Party's rights, hereunder, provided such directors, officers, employees, agents, consultants, subcontractors or other Persons are subject to confidentiality obligations applicable to such Confidential Information no less strict than those set forth herein, (ii) as approved by the Disclosing Party hereunder in writing, (iii) as set forth elsewhere in this Agreement, including to subcontractors and sublicensees in accordance with Section 7.2, (iv) to file or prosecute Patent Rights in accordance with this Agreement, (v) to prosecute or defend litigation as permitted by this Agreement, (vi) to any Governmental Authority or other Regulatory Authority in order to gain or maintain approval to conduct clinical trials or to market Co-Funding Products, but such disclosure may be only to the extent reasonably necessary to obtain such approvals (subject to the applicable provisions of Article 3, Article 4, Article 5 and Article 8 as and to the extent applicable), or (vii) as required by Applicable Law, valid order of a court of competent jurisdictions, or other judicial or administrative proceedings of any Governmental Authority requires to be disclosed, provided that in the case of (v), (vi) or (vii) the Receiving Party gives the Disclosing Party reasonable advance notice (if practical) of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provided further that the Receiving Party provides all reasonable cooperation to assist the Disclosing Party to protect such information and limits the disclosure to that information which is required by Applicable Law to be disclosed, and also provided that, such information shall still be treated as Confidential Information for all purposes other than satisfaction of such disclosure requirement.

(d) Other [***] shall be Confidential Information of both Parties; provided that the [***] may be utilized as provided in (c) above, as well as, the following: (i) used by either Party (or their respective subcontractors, licensees or sublicensees) but not disclosed to Third Parties except as other Confidential Information may be disclosed by the Receiving Party (a) as expressly permitted herein (including through the publication procedures set forth in Section 13.4) or (b) with the prior written consent of the other Party; (ii) disclosed under commercially reasonable confidentiality terms and solely to the extent reasonably necessary to any potential or actual investor, advisor, lender, investment banker, financing partner, or acquirer; and (iii) disclosed under confidentiality obligations at least as restrictive as, or substantially the same as, those set forth herein (except with respect to the duration of such obligations, which shall not be less than [***] from the date that the agreement under which such information is disclosed), to any actual or prospective subcontractor, licensee or sublicensee. Notwithstanding the foregoing or anything to the contrary contained herein, (A) (I) Regeneron Materials Improvements, Know-How within the Regeneron Contributed Technology and Know-How within the Regeneron Co-Funding Product Inventions to the extent solely owned by Regeneron and (II) any other Confidential

Information to the extent related to Regeneron Co-Funding Products or Regeneron Co-Funding Targets, shall be the Confidential Information of Regeneron, and (B)(I) Intellia Know-How [***], (II) Intellia Materials Improvements and Know-How within the Intellia Co-Funding Product Inventions to the extent solely owned by Intellia and (III) any other Confidential Information to the extent related to Intellia Co-Funding Products or Intellia Co-Funding Targets, shall be the Confidential Information of Intellia.

13.2 Exceptions. Section 13.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

13.3 Injunctive Relief. Section 13.3 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

13.4 Publications.

(a) [***]. Subject to the prior written consent of the JSC and subject further to Sections 13.4(b) and 13.4(c), either Party may issue publications in scientific journals and make scientific presentations [***] with the order and inclusion of Intellia and Regeneron authors to be agreed upon in accordance with International Committee of Medical Journal Editors (ICJME) Standards or other mutually agreed upon applicable standards and in compliance with any applicable rules or policies of the publisher of such publication.

(b) Co-Funding Products, Co-Funding Targets and Co-Funding Product Inventions. Subject to Section 13.4(c), Regeneron shall have the sole right to issue and control all publications in scientific journals and make scientific presentations regarding [***], and to extent Intellia contributes to such publication, the order and inclusion of Regeneron and Intellia authors to be agreed upon in accordance with International Committee of Medical Journal Editors (ICJME) Standards or other mutually agreed upon applicable standards and in compliance with any applicable rules or policies of the publisher of such publication.. Subject to Section 13.4(c), Intellia shall have the sole right to issue and control all publications in scientific journals and make scientific presentations regarding [***], and to extent Regeneron contributes to such publication, the order and inclusion of Intellia and Regeneron authors to be agreed upon in accordance with International Committee of Medical Journal Editors (ICJME) Standards or other mutually agreed upon applicable standards and in compliance with any applicable rules or policies of the publisher of such publication.

(c) Review Rights. If the JSC approves a publication under Section 13.4(a), Regeneron intends to make a publication under the first sentence of Section 13.4(b) or Intellia intends to make a publication under the second sentence of Section 13.4(b), the publishing Party shall provide the non-publishing Party an advance copy of any such proposed publication prior to submission for publication or disclosure. The non-publishing Party shall have a reasonable opportunity to (i) recommend any changes to prevent disclosure of its Confidential Information (including any joint Confidential Information) and (ii) file a Patent Application related to such Confidential Information, if any. The publishing Party shall remove any such Confidential

Information, and shall not make any such publication if the non-publishing Party requests a delay of up to [***] to enable it to file Patent Applications until expiration of [***] period.

13.5 Disclosures Concerning this Agreement.

(a) Press Releases. The Parties do not intend to issue a press release announcing the execution of this Agreement. Excluding the first sentence, the remainder of Section 13.5(a) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

(b) Agreement Terms. Except as required by a Governmental Authority or Applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are or will be traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any terms of this [***] that have not been previously disclosed publicly in accordance with this Article 13 without the prior written consent of the other Party, which consent shall not be unreasonably conditioned, withheld or delayed; except for disclosures thereof pursuant to Section 7.3(e) of this Agreement or (i) to potential or actual investors, advisors, lenders, investment bankers, financing partners, acquirers, subcontractors, licensees or sublicensees that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least [***] (but of shorter duration if customary in connection with any disclosure to a potential or actual investor, advisor, lender, investment banker or financing partner) or (ii) to Persons that are identified in Section 13.1(c)(i) who are subject to the confidentiality obligations specified therein; provided that, in the event of any such disclosure to a Third Party who is a potential or actual investor, advisor, lender, financing partner, acquirer, licensee or sublicensee (A) this Agreement shall only be initially disclosed in the Redacted Agreement form to such Third Party and its advisors and (B) after negotiations with any such Third Party have progressed so that the Disclosing Party reasonably and in good faith believes it will execute a definitive agreement with such Third Party within [***], this Agreement may be disclosed in an unredacted form to such Third Party and its advisors as and to the extent relevant to such Third Party [***].

(c) Communications General. Any mechanisms and procedures established by the JSC pursuant to Section 13.5(c) of the Collaboration Agreement to ensure coordinated timely corporate communications relating to the Collaboration Agreement shall also apply to this Agreement, including the Co-Funding Products.

(d) Publicly Traded Company. Each Party acknowledges that the other Party, as a publicly traded company, is legally obligated to make timely disclosures of all material events relating to its business. Therefore, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent (the "SEC"). The Parties agree that the form of the redacted version of this Agreement (the "Redacted Agreement"), which shall be mutually agreed by the Parties in good faith within [***] of the Effective Date, may be used as its filing (or submission) of this

Agreement to the SEC, and the Parties shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential information (including any information that constitutes a trade secret or a sensitive commercial term), including with respect to any comments received from the SEC with respect to the proposed redactions. The Parties further agree that, following the initial filing (or submission) of the Redacted Agreement, the filing Party will (i) promptly deliver to the non-filing Party any written correspondence received by the filing Party or its representatives from the SEC with respect to such confidential treatment request and promptly advise the non-filing Party of any other communications between the filing Party or its representatives with the SEC with respect to such confidential treatment request, allowing a reasonable time for the non-filing Party to review and comment; (ii) upon the written request of the non-filing Party, request an appropriate extension of the term of the confidential treatment period; and (iii) if the SEC requests any changes to the redactions set forth in the Redacted Agreement, to the extent reasonably practicable, not agree to any changes to the Redacted Agreement without first discussing such changes with the non-filing Party and taking the non-filing Party's comments into consideration when deciding whether to agree to such changes. In addition, each Party will provide the other Party with an advance copy of any securities filings in which the Agreement is discussed or disclosed, in each case only to the extent describing this Agreement or referencing the other Party, allowing a reasonable time (but in no event less than [***]) for the other Party to review and comment, and will reasonably consider and, to the extent permitted by a Governmental Authority, or Applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are or will be traded), incorporate the other Party's timely comments thereon; [***].

ARTICLE 14
INDEMNITY

14.1 Indemnity and Insurance.

(a) Intellia's Indemnification Obligations. Intellia will indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents ("Regeneron Indemnitees") from and against all loss, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), incurred by any Regeneron Indemnitee as a result of a Third Party's claim, action, suit, settlement, or proceeding (each, a "Claim") against a Regeneron Indemnitee that arises out of or results from:

(i) [***] of Intellia or any other Intellia Indemnitee(s) in its performance under the Plans or other activity under this Agreement, including in connection with the Development, Manufacture or Commercialization of any Co-Funding Product in the Field; or

(ii) breach by Intellia of this Agreement (including the inaccuracy of any representation or warranty made by Intellia in this Agreement);

in each case, except to the extent such Claim is subject to Regeneron's indemnification obligations under Section 14.1(b)(i) or (ii) below.

(b) Regeneron's Indemnification Obligations. Regeneron will indemnify and hold harmless Intellia, its Affiliates and their respective officers, directors, employees and agents ("Intellia Indemnitees") from and against all Damages incurred by any Intellia Indemnitee as a result of a Claim against an Intellia Indemnitee that arises out of or results from:

(i) [***] of any Regeneron or any other Regeneron Indemnitee(s) in its performance under the Plans or other activity under this Agreement, including in connection with the Development, Manufacture or Commercialization of any Co-Funding Product in the Field; or

(ii) breach by Regeneron of this Agreement (including the inaccuracy of any representation or warranty made by Regeneron in this Agreement);

in each case, except to the extent such Claim is subject to Intellia's indemnification obligations under Section 14.1(a)(i) or (ii) above.

(c) Product Liability. [***]. Regeneron shall have the sole right, but not the obligation, to defend any such Third Party product liability claim of a Regeneron Co-Funding Product. Intellia shall have the sole right, but not the obligation, to defend any such Third Party product liability claim of an Intellia Co-Funding Product. The non-defending Party shall provide reasonable cooperation and assistance to the defending Party.

14.2 Indemnity Procedure.

(a) Notification. The Party entitled to indemnification under this Article 14 (an "Indemnified Party") shall notify the Party potentially responsible for such indemnification (the "Indemnifying Party") within [***] Business Days of becoming aware of any Claim asserted or threatened in writing against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that such failure materially prejudices the Indemnifying Party.

(b) Control of Defense. If the Indemnifying Party elects in writing to the Indemnified Party that it will assume control of the defense of such Claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be conditioned, withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of such Claim within [***] of its receipt of notice thereof, or if the Indemnifying Party elects in

writing to the Indemnified Party to cease maintaining control of the defense of such Claim, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least [***] Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such Claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably conditioned, withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such Claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such Claim. The Indemnified Party may not compromise or settle such Claim without the prior written consent of the Indemnifying Party, such consent not to be unreasonably conditioned, withheld or delayed.

(c) Indemnified Party's Participation. The Indemnified Party shall cooperate with the Indemnifying Party in, and may participate in, but not control, any defense or settlement of any Claim controlled by the Indemnifying Party pursuant to this Section 14.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party (and the Out-of-Pocket Costs of the Indemnified Party shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses if the Claim is covered by Section 10.9 or Section 14.1(c)).

(d) Defense Procedures For Damages that are Other Shared Expenses. The indemnification procedures in this Section 14.2 shall apply to Claims for which each Party indemnifies the other Party for its Co-Funding Percentage subject to Section 9.3(b) of all Damages under the terms of Section 10.9 and Section 14.1(c); provided that Regeneron shall be deemed to be the Indemnifying Party if the Claim in Section 10.9 or Section 14.1(c) relates to a Regeneron Co-Funding Product and Intellia shall be deemed to be the Indemnifying Party if the Claim in Section 10.9 or Section 14.1(c) relates to an Intellia Co-Funding Product.

14.3 Insurance. During the Term and for a minimum period of [***] thereafter and for an otherwise longer period as may be required by Applicable Law, each of Regeneron and Intellia will (i) use Commercially Reasonable Efforts to procure and maintain appropriate commercial general liability and product liability insurance in amounts appropriate for the industry and considering the activities being conducted or (ii) with respect to Regeneron as of the Effective Date, or Intellia as such time as Intellia and its Affiliates have annual revenue in excess of [***] (including after any Change of Control of Intellia), procure and maintain adequate insurance by means of self-insurance in such amounts and on such terms as are consistent with normal business practices of large pharmaceutical companies in the life sciences industry. Such insurance shall insure against liability arising from this Agreement on the part of Regeneron or Intellia, respectively, or any of their respective Affiliates, due to injury, disability or death of any person or persons, or property damage arising from activities performed in connection with this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Section 14.1 or otherwise.

Any insurance proceeds received by a Party in connection with any Damages shall be retained by such Party and shall not reduce any obligation of the other Party.

ARTICLE 15
FORCE MAJEURE

Article 15 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

ARTICLE 16
TERM AND TERMINATION[3]

16.1 Term. The "Term" of this Agreement shall begin on the Effective Date and will expire with respect to all Co-Funding Products Directed to such Co-Funding Target at such time as neither the Lead Party nor any of its Affiliates, nor any of their respective sublicensees, is Developing, Commercializing and Manufacturing (for purposes of Development or Commercialization) any Co-Funding Product in the Field Directed to such Co-Funding Target anywhere in the world under this Agreement (and such cessation of Development, Manufacturing and Commercialization activities is acknowledged by the Lead Party in writing to be permanent), unless this Agreement is earlier terminated in its entirety in accordance with this Article 16, in which event the Term shall end on the effective date of such termination.

16.2 Termination for Insolvency. Section 16.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

16.3 Termination of Co-Funding Target for which a Party is the Lead Party for Convenience. At any time, upon [***] advanced written notice, with respect to all Co-Funding Products Directed to such Co-Funding Target, the Lead Party may terminate this Agreement with respect to the Co-Funding Target and all Co-Funding Products hereunder; provided, that, the Lead Party's obligation to use Commercially Reasonably Efforts to develop and commercialize Co-Funding Products with respect to a given Co-Funding Target and such Co-Funding Products shall continue during the [***] period following its delivery of such a notice of termination with respect to such terminated Co-Funding Target in accordance with this Agreement.

16.4 Termination of Co-Funding Target by the Participating Party for Convenience.

(a) The Participating Party may terminate this Agreement, (i) at any time upon [***] advanced written notice, (ii) within the first [***], pursuant to Section 3.2(b), (iii) [***]; or (iv) [***].

(b) With respect to termination under Section 16.4(a)(i) or Section 16.4(a)(ii), the Participating Party shall continue to be responsible for its share (applicable Co-Funding Percentage) of all Development Costs and Shared Commercial Expenses incurred in connection with the Co-Funding Product in accordance with the Global Development Budget set forth in the

[3] NTD: May be subject to further consideration by the parties as the draft progresses. In the final document, the termination scenarios will be included in the sub-annexes depending on the category of Co-Funding Target.

last Global Development Plan approved by the JSC and in accordance with the Global Commercialization Budget set forth in the last Global Commercialization Plan approved by the JSC and the Country/Region Commercialization Budget set forth in the last Country/Region Commercialization Plan approved by the JSC, including the U.S. Commercialization Budget set forth in the last U.S. Commercialization Plan, to the extent applicable, in each case prior to the Participating Party's notice of termination up until the effective date of termination in accordance with this Section 16.4.

(c) With respect to termination under Section 16.4(a)(iii) or Section 16.4(a)(iv), the Participating Party shall continue to be responsible for its share (applicable Co-Funding Percentage) of all Development Costs and Shared Commercial Expenses incurred in connection with the Co-Funding Product in accordance with the previously-approved Global Development Budget and in accordance with the previously-approved Global Commercialization Budget and the previously-approved Country/Region Commercialization Budget, including the previously approved U.S. Commercialization Budget, to the extent applicable, in each case prior to the Participating Party's notice of termination up until the effective date of termination in accordance with this Section 16.4. [***].

16.5 Breach of the Agreement.

(a) Either Party may terminate this Agreement in accordance with the remainder of this Section 16.5, its entirety if, as applicable, the other Party commits a material breach of this Agreement [***].

(b) In the event that one Party (the "Alleging Party") believes that the other Party (the "Alleged Party") has committed a material breach, the Alleging Party shall provide written notice ("Breach Notice") to the Alleged Party describing in an appropriate detail the nature of such material breach.

(c) The Alleged Party shall have [***] from its receipt of the Breach Notice to cure such material breach; provided that if such breach is not curable within the foregoing cure period, then such cure period will be extended for a period of up to [***] (for a total cure period of [***]) if the Alleged Party prepares and provides to the Alleging Party a reasonable written plan for curing such breach and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan. In the event such breach is not cured within such [***] period, as applicable, this Agreement or portion thereof, as applicable, may be terminated immediately by the Alleging Party.

(d) In the event of a good faith dispute as to the existence or materiality of a breach specified in such notice, including any good faith dispute as to payments due under this Agreement, and the Alleged Party provides the Alleging Party notice of such dispute within such [***] period, the cure period will be tolled from the date the Alleged Party notifies the Alleging Party of such good faith dispute and through the diligent resolution of such dispute in accordance with the applicable provisions of this Agreement (provided that if such dispute relates to payment, the cure period will only apply with respect to payment of disputed amounts, and not with respect

to undisputed amounts). It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations, and retain their respective rights, hereunder. Termination will become effective, if at all, following a final and conclusive determination pursuant to 17.1(c) of the Collaboration Agreement (which is incorporated into this Agreement in accordance with Section 17.1) that the Alleged Party committed such material breach and failed to cure the same during the applicable cure period.

16.6 Termination for IP Challenge. With respect to Co-Funding Products, Section 16.5 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and all references to Regeneron Target or Regeneron Product therein shall be deemed to refer to the Co-Funding Target and Co-Funding Product(s) respectively.

16.7 Termination for Suspension of Development or Commercialization. If during the period after the Effective Date, the Lead Party elects to permanently discontinue all Development, Commercialization and Manufacturing (for purposes of Development or Commercialization) of all Co-Funding Products Directed to the Co-Funding Target it shall provide written notice to the Participating Party which will automatically be treated as the Lead Party's submission of written notice pursuant to Section 16.3 with respect to the Co-Funding Target.

16.8 Effects of Termination of the Agreement where Regeneron is the Lead Party, except if the Agreement is Terminated by Intellia pursuant to Section 16.4.

(a) If this Agreement is terminated by either Party with respect to a Co-Funding Target for which Regeneron is the Lead Party for any reason other than by Intellia pursuant to Section 16.4 then the following provisions of this Section 16.8(a) will apply, subject to Section 16.8(b):

(i) This Agreement shall terminate in its entirety with respect to such Terminated Co-Funding Target and Terminated Co-Funding Products, including the licenses granted to the Parties under [***].

(ii) Sections 16.7(c)-(l) of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) (including all provisions in the Collaboration Agreement that are incorporated by reference into such provisions), except that (A) references to the Terminated Regeneron Target in such provisions shall be deemed to refer to the Terminated Co-Funding Target and (B) Regeneron's interest in and to the Converted CFP Inventions shall be included within the Collaboration Reversion IP thereunder. [***].

(iii) Regeneron shall assign to Intellia all right, title and interest in the Intellia Material Improvements within Co-Funding Product Inventions that solely relates to the Terminated Co-Funding Products.

(b) If this Agreement is terminated by Regeneron pursuant to Section 16.5 (Breach), then, (i) this Agreement shall terminate in its entirety with respect to such Terminated Co-Funding Target, and Terminated Co-Funding Products, including the licenses granted to the Parties [***], and (ii) Regeneron may elect (which election shall be made in writing by Regeneron no later than [***] of such determination thereof and no later than the effective date of termination of this Agreement) that the Collaboration Agreement (and all the terms and conditions therein) shall be deemed to apply to such Terminated Co-Funding Target and all Terminated Co-Funding Products that are Directed to such Terminated Co-Funding Target, and upon such election, the Terminated Co-Funding Target shall become a Regeneron Target and all associated Terminated Co-Funding Products shall be deemed to be Regeneron Products [***]. It is understood and agreed by the Parties that Regeneron may only Develop, Manufacture or Commercialize CPs (including Terminated Co-Funding Products) Directed to such Terminated Co-Funding Target by electing this option. [***].

16.9 Effects of Termination of the Agreement where Regeneron is the Lead Party if the Agreement is Terminated by Intellia pursuant to Section 16.4. Without limiting any other legal or equitable remedies that either Party may have, if this Agreement with respect to a Co-Funding Target for which Regeneron is the Lead Party is terminated by Intellia pursuant to Section 16.4, then this Agreement shall terminate in its entirety with respect to such Terminated Co-Funding Target and Terminated Co-Funding Products, including the licenses granted to the Parties under [***], and the Collaboration Agreement (and all the terms and conditions therein) shall be deemed to apply to such Terminated Co-Funding Target and all Terminated Co-Funding Products that are Directed to such Terminated Target, and such Terminated Co-Funding Target shall be considered a Regeneron Target and all Terminated Co-Funding Products shall be deemed to be Regeneron Products.

16.10 Effects of Termination of the Agreement where Intellia is the Lead Party, except if the Agreement is Terminated by Intellia pursuant to Section 16.3 or Section 16.7 or the Agreement is Terminated by Regeneron pursuant to Section 16.4. If this Agreement with respect to a Co-Funding Target for which Intellia is the Lead Party is terminated by either Party for any reason other than by Intellia pursuant to Section 16.3 or Section 16.7 or by Regeneron pursuant to Section 16.4 then the provisions of this Section 16.10 will apply:

(a) This Agreement shall terminate in its entirety, including the licenses granted under [***].

(b) Section 16.12(a) through 16.12(c) shall apply.

(c) Intellia shall assign to Regeneron all right, title and interest in the Regeneron Material Improvements within Co-Funding Product Inventions that solely relates to the Terminated Co-Funding Products, and such Regeneron Material Improvements shall be deemed to be Regeneron Contributed IP for purposes of Section 16.12(c).

16.11 Effects of Termination of the Agreement where Intellia is the Lead Party if this Agreement is Terminated by Intellia pursuant to Section 16.3 or Section 16.7. With respect to Intellia Co-Funding Targets and Intellia Co-Funding Products, without limiting any other legal

or equitable remedies that either Party may have, if this Agreement is terminated by Intellia pursuant to Section 16.3 or Section 16.7, then the provisions of this Section 16.11 will apply:

(a) This Agreement shall terminate in its entirety, including the licenses granted under [***], and the Collaboration Agreement (and all the terms and conditions therein) shall be deemed to apply to such Terminated Target and all Terminated Co-Funding Products, and such Terminated Target shall be deemed to be a Regeneron Target and the Terminated Co-Funding Products shall be deemed to be Regeneron Products and Section 16.7(d)-(l) of the Collaboration Agreement shall apply *mutatis mutandis* so that Regeneron may assume development and commercialization of Terminated Co-Funding Products as Regeneron Products thereunder. [***].

(b) Intellia shall assign to Regeneron all right, title and interest in the Regeneron Material Improvements within Co-Funding Product Inventions that solely relates to the Terminated Co-Funding Products.

16.12 Effects of Termination of the Agreement where Intellia is the Lead Party if this Agreement is Terminated by Regeneron pursuant to Section 16.4. With respect to Intellia Co-Funding Targets and Intellia Co-Funding Products, without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated by Regeneron pursuant to Section 16.4, then the provisions of this Section 16.12 will apply:

(a) This Agreement shall terminate in its entirety with respect to such Terminated Co-Funding Target and all Terminated Co-Funding Products Directed to such Terminated Target, including the licenses granted under [***].

(b) [***], all such Terminated Co-Funding Products shall be subject to the payment by Intellia to Regeneron of royalties on Net Sales of such Terminated Co-Funding Products at the rate set forth in the table below based on the stage of the most advanced Terminated Co-Funding Product Directed to the applicable Terminated Co-Funding Target and Regeneron's Co-Funding Percentage, in each case, as of the effective date of termination with respect to such Terminated Co-Funding Target and Section 16.7(c)(v) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) (including all provisions in the Collaboration Agreement that are incorporated by reference into such provisions), [***].

Stage	**Royalty Rate** [***]	**Royalty Rate** [***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

(c) Effective upon the effective date of termination, Regeneron shall grant, and hereby grants, to Intellia a perpetual, irrevocable, worldwide, sublicensable through multiple tiers (in accordance with Section 7.2(c) of the Collaboration Agreement applied *mutatis mutandis*), non-exclusive license under the [***] to research, develop, make, have made, use, sell, offer for sale and import Terminated Co-Funding Products for any and all uses in the Field.

(d) Intellia shall assign to Regeneron all right, title and interest in the Regeneron Material Improvements within Co-Funding Product Inventions that solely relates to the Terminated Co-Funding Products, and such Regeneron Material Improvements shall be deemed to be Regeneron Contributed IP for purposes of Section 16.12(c).

16.13 Participating Party's Remedies in lieu of Termination.

(a) In the event that the Participating Party notifies the Lead Party in writing that Lead Party has materially breached this Agreement such that the Participating Party would have a right of termination pursuant to Section 16.5 as a result of such material breach (including the application of Section 16.5(b)) [***], then, in lieu of the Participating Party exercising such termination right pursuant to Section 16.5, the Participating Party may elect to enter into a new agreement using the form of this agreement with the relevant provisions for the Co-Funding Product (which election shall be made in writing by the Participating Party no later than [***] of such determination thereof); provided, however, that if the Participating Party so elects to enter into a new agreement, then with respect to such Co-Funding Target for which the Lead Party has materially breached this Agreement and for all CPs that are Directed to such Co-Funding Target, such Co-Funding Target and such CPs Directed thereto shall become upon written notice delivered to such breaching Lead Party, (i) in the case where Intellia is the breaching Lead Party, a Regeneron Co-Funding Target and Regeneron Co-Funding Products or (ii) in the case where Regeneron is the breaching Lead Party, Intellia Co-Funding Target and Intellia Co-Funding Products, as applicable, and it shall be treated as if the breaching Lead Party had terminated this Agreement pursuant to Section 16.3 and Section 16.11 or Section 16.8(a) (as applicable) shall apply *mutatis mutandis* and the Participating Party making such election to so enter into a new agreement shall from and after such date be the Lead Party and the breaching Lead Party shall thereafter be the Participating Party with respect to such Co-Funding Target and all CPs Directed to such Co-Funding Target. In connection with such changing roles of the Lead Party and Participating Party in the new agreement, the Parties agree that over a [***] to transfer all rights, obligations, commitments and operations between the Parties to reflect the change in the Lead Party. The former Lead Party shall, as promptly as reasonably practicable, transfer all Patent prosecution and maintenance responsibilities for Co-Funding Product Inventions to the former Participating Party, including transferring all files related to the prosecution and maintenance of such Patents to the former Participating Party and at the request of the former Participating Party, make appropriate personnel available to the former Participating Party to answer such reasonable questions as the former Participating Party may have in connection with the prosecution and maintenance of such Patents. [***].

(b) [***].

16.14 Change of Control of the Participating Party. In the event of a Change of Control of the Participating Party during the Term, the Participating Party shall deliver to the Lead Party written notice of the closing of such transaction within [***] following such closing. If, as of the closing of such Change of Control of the Participating Party, the Lead Party or any of its Affiliates is in litigation that is material to the Lead Party or its Affiliate, or has initiated or received notice of a claim, action, suit, or proceeding, or has sent or received a demand letter, that is reasonably likely to result in litigation that is material to the Lead Party or its Affiliate, with the Third Party

or its Affiliate (other than a Party or a Party's Affiliates immediately prior to the closing of such Change of Control) involved in such Change of Control of the Participating Party (the "Subject Litigation"), then [***].

(a) [***].

(b) [***].

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***];

(vi) [***]; and

(vii) [***].

[***].

16.15 Survival of Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination. Except for the following provisions (which shall survive expiration or termination of this Agreement), upon expiration or termination of this Agreement, the rights granted to the Parties hereunder and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect: (I) Section 2.2(a), Section 2.2(b), Sections 5.3 and 5.4 (until the Development and Commercialization of the Co-Funding Products have been transferred to the Party that will continue to be responsible for such Development and Commercialization after termination of this Agreement), Section 7.1, Section 7.2(a), Section 7.2(c), Section 7.6 (for the period set forth therein), Section 7.7, Section 7.12(a) (only with respect to the incorporation of Section 7.12 of the Collaboration Agreement), Section 9.4 and Section 9.6 (with respect to the final Quarter of the Term), Section 9.8, Section 9.9, Section 9.10, Section 9.11, Section 10.1, Section 13.1, Section 13.2, Section 13.3, [Section 16.8, Section 16.9, Section 16.10, Section 16.11, Section 16.12,][4] Section 16.15, and Section 16.16; (II) Sections 10.2, 10.3, 10.4, 10.6, 10.7, 10.8, and 10.9 solely with respect to Intellectual Property covered by this Agreement that is jointly owned by the Parties pursuant to the terms of this Agreement; and (III) Article 1 (to the extent necessary to give effect to the other surviving provisions), Article 11, Article 14, Article 15, and

[4] NTD: To be updated in each Co-Co Agreement, as applicable.

Article 17. In addition, the other applicable provisions of Article 9 will survive such expiration or termination of this Agreement to the extent required to make final reimbursements, reconciliations or other payments incurred or accrued prior to the date of termination or expiration or after such termination or expiration with respect to Section 16.7 (including any milestone payments and royalties that become due as a result of Section 16.7(i)). For any surviving provisions requiring action or decision by a Committee or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable.

16.16 Return of Confidential Information. Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Upon the expiration or termination of this Agreement, and [***], the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof) pertaining to the expired or terminated subject matter and, if expressly requested in writing by the Disclosing Party, provide the Disclosing Party with written certification of such destruction within [***]; provided, that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement; further provided that the Receiving Party may retain the Disclosing Party's Confidential Information that is necessary or useful for the practice of any license from the Disclosing Party to the Receiving Party that survives expiration or termination, as applicable. [***].

ARTICLE 17
MISCELLANEOUS

17.1 Governing Law; Dispute Resolution; Submission to Jurisdiction. Section 17.1 of the Collaboration Agreement is hereby incorporated by reference into this Agreement, except that the reference in Section 17.1(b) of the Collaboration Agreement to Section 16.9 shall be deemed to refer to Section 16.14 of this Agreement. For clarity, Section 17.1(b) of the Collaboration Agreement shall apply to unresolved Financial Disputes.

17.2 Waiver. Section 17.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.3 Notices. Section 17.3 (including Schedule 17.3) of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.4 Entire Agreement. The first sentence of Section 17.4 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.5 Amendments. Section 17.5 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.6 Interpretation. Section 17.6 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.7 Construction. Section 17.7 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.8 Severability. Section 17.8 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.9 Assignment. Section 17.9 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.10 Successors and Assigns. Section 17.10 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.11 Counterparts. Section 17.11 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.12 Third Party Beneficiaries. Section 17.12 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.13 Relationship of the Parties. Section 17.13 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.14 Limitation of Damages. Section 17.14 of the

Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.15 Injunctive or Other Equity Relief. Section 17.15 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

17.16 Non-Exclusive Remedies. Section 17.16 of the Collaboration Agreement is hereby incorporated by reference into this Agreement.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Regeneron and Intellia have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

REGENERON PHARMACEUTICALS, INC.

By _____
Name:
Title:

INTELLIA THERAPEUTICS, INC.

By _____
Name:
Title:

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Schedule 1.18

Co-Funding Target

Schedule 1.18

Schedule 1.102

Manufacturing Cost

Manufacturing Cost as used in this Agreement shall be determined as provided in this Schedule 1.102.

"Manufacturing Cost" means the [***].

(a) "Direct Costs" equals the sum of the following:

(i) [***].

(ii) [***].

(iii) [***].

(iv) [***].

(v) [***].

(b) "Indirect Costs" equals the sum of the following:

(i) [***].

(ii) [***].

[***]

1. [***]
2. [***]
3. [***]
4. [***]
5. [***]

Schedule 1.102

Schedule 9.2

[***]

[***]

Definitions:

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

"Total Development Costs" means the aggregate of Development Costs incurred by both Regeneron and Intellia for a Co-Funding Product.

[***]

"Profits" in a [***] means for a particular Co-Funding Product the Co-Funding Product Net Sales recorded by the Lead Party worldwide in the Quarter less the sum of (a) Cost of Goods incurred by the Lead Party world-wide in the Quarter, (b) Shared Commercial Expenses incurred by both Parties in the [***], and (c) Other Shared Expenses incurred by both Parties in the [***].

"Lead Party [***] Expenses" is the sum of the amounts in (a), (b) and (c) in the definition of Profits that are incurred by the Lead Party in a [***] for a Co-Funding Product.

"Participating Party [***] Expenses" shall be the sum of the amounts in (a), (b) and (c) in the definition of Profits that are incurred by the Participating Party in a [***] for a Co-Funding Product.

"Profit Split" for a Co-Funding Product means the product of (i) Profits in a [***] worldwide, (ii) the Participating Party Co-Funding Percentage, and (iii) -1.

"[***] Profit True-Up" for a Co-Funding Product means (i) the Profit Split minus (ii) Participating Party Quarterly Expenses.

Examples

In all of the examples below, it is assumed that the Participating Party Co-Funding Percentage is [***] for a given Co-Funding Product:

- [***] Development True-Up for Co-Funding Product A Example:

	Aggregate	Lead Party	Participating Party
Development Costs	[***]	[***]	[***]
Total Development Costs	[***]		

[***] Development True-Up = [***]

[***]

In this example, [***] would be included in the Aggregate [***] True-Up for Co-Funding Product A.

- [***] Development True-Up for Co-Funding Product B Example:

	Aggregate	Lead Party	Participating Party
Development Costs	[***]	[***]	[***]
Total Development Costs	[***]		

[***] Development True-Up = [***]
[***]

In this example, [***] would be included in the Aggregate [***] True-Up for Co-Funding Product B.

- [***] Profit True-Up Examples:
  - Co-Funding Product A: Calculation of the Profit Split in a Quarter:

	Aggregate	Lead Party	Participating Party
Co-Funding Product Net Sales	[***]	[***]	
(-) Cost of Goods Sold	[***]	[***]	
(-) Shared Commercial Expenses	[***]	[***]	[***]
(-) Other Shared Expenses	[***]	[***]	[***]
Profits	[***]		

Profit Split = [***].

[***] Profit True-Up = [***]
[***]

In this example, [***] would be included in the Aggregate [***] True-Up for Co-Funding Product A.

  - Co-Funding Product B Example: Calculation of the Profit Split in a Quarter in which there are no Co-Funding Product Net Sales:

	Aggregate	Lead Party	Participating Party
Co-Funding Product Net Sales	[***]	[***]	[***]

(-) Cost of Goods Sold	[***]	[***]	[***]
(-) Shared Commercial Expenses	[***]	[***]	[***]
(-) Other Shared Expenses	[***]	[***]	[***]
Profits	[***]		

Profit Split = [***].

Quarterly Profit True-Up = [***]
[***]

In this example, [***] would be included in the Aggregate [***] True-Up for Co-Funding Product B.

- Aggregate [***] True-Up Example:

[***] Development True-Up for Co-Funding Product A [***]
[***] Development True-Up for Co-Funding Product B [***]
[***] Profit True-Up for Co-Funding Product A [***]
[***] Profit True-Up for Co-Funding Product B [***]

Aggregate [***] True-Up [***]

In this example, [***] would be payable by the Lead Party to the Participating Party in accordance with the terms of Article 9 and this Schedule 9.2.

Combination Products.

In the event a Co-Funding Product is a Combination Product [***].

In the event a Co-Funding Product is a Combination Product [***].

Schedule 9.2

ANNEX 1

Provisions Specific to Categories of Products

This Annex is divided into four (4) sub-annexes. The Sections set forth in sub-annex (A), (B), (C) or (D) shall be inserted into the corresponding Sections of this Agreement prior to execution for the applicable Co-Funding Target, depending on whether the Co-Funding Target is:

(A) **Regeneron Co-Funding Target where a Regeneron Target is the Co-Funding Target;**

(B) **Regeneron Co-Funding Target where an Intellia Liver Target is the Co-Funding Target;**

(C) **Intellia Co-Funding Target; or**

(D) **TTR.**

For clarity, for each Co-Funding Target, only one of the four (4) above sub-annexes shall apply.

SUB-ANNEX 1(A):

Regeneron Co-Funding Target where a Regeneron Target is the Co-Funding Target

1.17 "Co-Funding Product" shall mean each Regeneron Co-Funding Product that is Directed to the Co-Funding Target.

1.27 "Converted CFP Inventions" means the Co-Funding Product Inventions which become Other Co-Funding Product Inventions by operation of Section 10.1(a)(iii) upon termination of this Agreement.

1.38

4. [Intentionally Omitted]

1.44 "Exercised Option" shall mean the Intellia Option, exercised by Intellia under Section 5.2(c) of the Collaboration Agreement, in accordance with the Collaboration Agreement, for the Target set forth on Schedule 1.44 of this Agreement.

1.89 "IP Term" shall mean that period, during the Term, commencing on the Effective Date and continuing for [***] to such Co-Funding Target.

1.94 "Lead Party" shall mean Regeneron.

1.115 "Participating Party" shall mean Intellia.

2.2(b) There are instances where certain provisions of this Agreement only apply to Regeneron Co-Funding Products and not to Intellia Co-Funding Products and where such provisions were already set forth in the Collaboration Agreement with respect to Regeneron Products. In such cases, this Agreement incorporates by reference the applicable terms of the Collaboration Agreement, except that references to Regeneron Products in the applicable terms of the Collaboration Agreement shall be deemed to refer to Regeneron Co-Funding Products and references to the Collaboration Agreement in the applicable terms of the Collaboration Agreement shall be deemed to refer to this Agreement.

2.4(b)(viii) [Intentionally Omitted]

2.9 [Intentionally Omitted]

3.1 Development of Co-Funding Products. Subject to the terms of this Agreement, the Lead Party shall undertake, and in accordance with Section 3.2 with respect to a Regeneron Co-Funding Product, the Parties shall jointly undertake Development activities with respect to Co-Funding Products unless otherwise mutually agreed to in the Global Development Plan, and such Development activities shall be under the general direction and oversight of the JDC and JSC. [***]. Except as set forth in Section 3.2 with respect to a Regeneron Co-Funding Product or otherwise agreed to by the Parties in writing or explicitly set forth in this Agreement, the JSC will assign responsibility for conducting all Development activities for a Co-Funding Product to the

Lead Party. For clarity, with respect to a given Regeneron Product that constitutes a Co-Funding Product under this Agreement, the diligence obligations of Regeneron to develop and commercialize such Regeneron Product in Sections 4.4(d) and 6.1(a) of the Collaboration Agreement shall be superseded (from and after the Effective Date of this Agreement) by Regeneron's diligence obligations as a Lead Party for such Co-Funding Product under this Agreement, [***].

3.2 Existing Product R&D Programs and Associated Product R&D Plans.

(a) With respect to a Co-Funding Product that constituted a Regeneron Product immediately prior the Effective Date of this Agreement, if a Product R&D Program and an associated Product R&D Plan existed immediately prior to Option Exercise Date for a Regeneron Product that becomes a Regeneron Co-Funding Product on account of Intellia's exercise of the Exercised Option, to the extent applicable, such Product R&D Program and associated Product R&D Plan shall be incorporated and made a part of the Global Development Plan for the relevant Regeneron Co-Funding Product and Section 4.3(b), 4.4(a), 4.4(d), 4.4(e) and 4.6(b) of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). [***].

(b) The Participating Party may terminate this Agreement with respect to the Co-Funding Target and all Co-Funding Products Directed to such Co-Funding Target any time [***]. Upon such termination, the Regeneron Option exercised in conjunction with this Agreement shall no longer constitute one of the Regeneron Options exercised by Regeneron under Section 5.1 of the Collaboration Agreement. For clarity, each Party shall be responsible for the costs incurred under this Agreement through the date of termination in accordance with their respective Co-Funding Percentages.

3.3 [Intentionally Omitted]

3.4 [Intentionally Omitted]

3.5 [Intentionally Omitted]

3.6(b) [Intentionally Omitted]

3.8 Intellia Technical Support Related to the Development of Regeneron Co-Funding Products. With respect to Regeneron Co-Funding Products, Section 6.1(b) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). Costs incurred by Intellia in the conduct of activities conducted pursuant to this Section 3.8 shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses.

5.1(b)(ii) Regeneron shall be responsible for all communications with Regulatory Authorities in connection with Regeneron Co-Funding Products, with Intellia's support and input (which may include preparation by Intellia of [***]), which support and input shall be provided by Intellia upon reasonable request by Regeneron; provided, that, in connection with such support prior to commencing such support, [***]. Costs incurred by Intellia in the conduct of the assistance contemplated by the previous sentence shall constitute Development Costs and shall be shared by the Parties in accordance with their respective Co-Funding Percentages.

5.1(c) [Intentionally Omitted]

6.3 [Intentionally Omitted]

6.4 In the event that either (a) the use, practice or exercise by Regeneron (or any of its Affiliates or sublicensees) of any Intellia Intellectual Property in accordance with the licenses expressly granted to Regeneron in accordance with this Agreement or (b) the research, development, making, having made, use, sale, offering for sale, or import by Regeneron (or any of its Affiliates or sublicensees) of a Regeneron Co-Funding Product [***] for use in the Field, pursuant to, and in accordance with, this Agreement, would infringe or misappropriate any Patent Right which is first Controlled by Intellia or its Affiliates after the IP Term and which is not covered by the license grant in Section 6.1, Intellia shall grant, and hereby grants, to Regeneron a non-exclusive, royalty-free, worldwide, sublicensable in multiple tiers (in accordance with Section 7.2(c) license under such Patent Right solely as necessary to (i) use, practice and exercise the Intellia Intellectual Property in accordance with the licenses expressly granted to Regeneron in accordance with this Agreement and (ii) research, develop, make, have made, use, sale, offer for sale, and import Regeneron Co-Funding Products for use in the Field in accordance with this Agreement, and solely for such purpose. The foregoing license under this Section 6.4 shall automatically terminate on a Regeneron Co-Funding Target-by-Regeneron Co-Funding Target basis (and with respect to all Regeneron Co-Funding Products Directed to such Co-Funding Target) simultaneous with the termination of the license under Section 6.1 with respect to such Regeneron Co-Funding Product. [***].

7.2(c)(ii) [***].

7.3(d) [***].

7.4(b) With respect to the Regeneron Co-Funding Products, the second sentence of Section 7.4(a) and Section 7.4(b) of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and any payments made by Regeneron in accordance Section 7.4(a) of the Collaboration Agreement shall be considered Third Party License Payments and shall be treated in accordance with Section 7.5.

7.11 Ongoing Technology Update and Transfer Obligations. With respect to the Co-Funding Products, Section 7.11 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). Costs incurred by Intellia in the

performance of activities conducted pursuant to clause (c) of Section 7.11 of the Collaboration Agreement shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses.

7.12 [Intentionally Omitted]

8.1 Non-GMP Manufacture of Co-Funding Products. With respect to the Regeneron Co-Funding Products, Section 8.1 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

8.2 Section 8.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). [***].

8.3(b) With respect to a Regeneron Co-Funding Product, the second and third sentences of Section 8.3 of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

8.4 Manufacturing Process Technology Transfer. With respect to the Regeneron Co-Funding Products, [***].

9.1 Reimbursement for Past Expenses. Within [***] after the Effective Date of this Agreement, the Party that exercised the Exercised Option, as applicable, shall pay to the other Party an amount equal to [***].

9.13 Effect of Amendment of the UC Technology License. [***].

9.14 Treatment of Certain Payments for Sharing of Profits and Development Costs for Regeneron Co-Funding Products. With respect to Regeneron Co-Funding Products [***].

10.12(b) In the event that Regeneron is not fully able to enjoy any rights granted Regeneron under this Article 10 as a result of the provisions of this Section 10.12, then Intellia shall use diligent efforts to afford and allow Regeneron to exercise and enjoy such rights to the maximum extent possible under the applicable Third Party agreement (but Intellia shall not be required to amend or otherwise modify any such agreement, or make any payments to such Third Party), [***].

12.2 Additional Representations, Warranties and Covenants of the Parties.

(a) [Intentionally Omitted]

(b)

(i) Except as set forth on Schedule 12.2(b)(i), Regeneron additionally hereby represents and warrants to Intellia, as modified by any exceptions to such representations and warranties applied *mutatis mutandis* to the subject matter of the Intellia Option as set forth in the Option Package for the Co-Funding Target and Co-Funding Products, that as of the Option Exercise Date:

(1) There are no claims, judgments or settlements against or owed by Regeneron (or any of its Affiliates) and no pending or, to Regeneron's knowledge, threatened (in writing) claims or litigation, in each case, to which Regeneron (or its Affiliates,) is a party or threatened (in writing) party relating to the Regeneron Contributed IP or otherwise challenging Regeneron's ownership or control of the Regeneron Contributed IP, in each case, with respect to the foregoing, solely with respect to the Co-Funding Products (such Regeneron Contributed IP, the "CFP Regeneron Contributed IP");

(2) Schedule 12.2(b)(i)(2)(A) sets forth a true, correct and complete list of Patent Rights within the CFP Regeneron Contributed IP existing as of the Option Exercise Date, in each case, with respect to the foregoing, solely with respect to the Co-Funding Products (the "CFP Regeneron Patent Rights"). To the knowledge of the individuals listed on Schedule 12.2(b)(i)(2)(B) (without any duty to inquire), the CFP Regeneron Patent Rights exist and are not invalid or unenforceable, in whole or in part;

(3) Regeneron solely owns all CFP Regeneron Contributed IP; and Regeneron Controls all of the CFP Regeneron Patent Rights;

(4) Schedule 12.2(b)(i)(4) sets forth a true, correct and complete list of all agreements pursuant to which Regeneron has in-licensed, or otherwise obtained rights to, CFP Regeneron Contributed IP (the "Regeneron Agreements");

(5) Regeneron is not aware of any claim made in writing against it asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of the CFP Regeneron Patent Rights;

(6) Neither Regeneron nor any of its Affiliates is or has been a party to any agreement with the U.S. federal government or an agency thereof pursuant to which the U.S. federal government or such agency provided funding for the development of the CFP Regeneron Contributed IP;

(7) Neither Regeneron nor any of its Affiliates has received any written notification from a Third Party that the use of any CFP Regeneron Contributed IP infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party;

(8) The CFP Regeneron Contributed IP is not subject to any liens or encumbrances or other grants in favor of any Third Party that conflicts with the rights or licenses granted to Intellia under this Agreement;

(9) To the knowledge of the individuals listed on Schedule 12.2(b)(i)(9) [***], the conception, discovery, development or reduction to practice of CFP Regeneron Contributed IP has not constituted or involved misappropriation of Intellectual Property or rights of any Person; and

(10) Regeneron has a right and license to use the Patent Rights that are licensed to Regeneron (directly or indirectly) under each of the Regeneron Agreements on a worldwide basis, and Regeneron is granting a sublicense to such Patent Rights to Intellia for use on a worldwide basis, in each case, with respect to the foregoing, solely with respect to the Co-Funding Products.

(ii) With respect to each of the Regeneron Agreements (as may be amended from time to time), Regeneron hereby represents and warrants as of the Effective Date, and covenants during the Term, to Intellia that:

(1) Sections 12.4(a)(i) and (ii) of the Collaboration Agreement (as applied *mutatis mutandis*) are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), in each case, with respect to the foregoing, solely with respect to the Co-Funding Products; and

(2) Regeneron shall fulfill all of its material obligations, including its payment obligations, under the Regeneron Agreements, with respect to the Co-Funding Products.

12.3(d) Covenants.

(i) With respect to the Regeneron Co-Funding Products under this Agreement, [***].

(ii) Section 12.4 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

SUB-ANNEX 1(B):

Regeneron Co-Funding Target where an Intellia Liver Target is the Co-Funding Target

1.17 "Co-Funding Product" shall mean each Regeneron Co-Funding Product that is Directed to the Co-Funding Target.

1.27 "Converted CFP Inventions" means the Co-Funding Product Inventions which become Other Co-Funding Product Inventions by operation of Section 10.1(a)(iii) upon termination of this Agreement.

1.38

4. [Intentionally Omitted]

1.44 "Exercised Option" shall mean the Regeneron Option exercised by Regeneron under Section 5.1(e) of the Collaboration Agreement, in each case, in accordance with the Collaboration Agreement, for the Target set forth on Schedule 1.44 of this Agreement.

1.89 "IP Term" shall mean that period, during the Term, commencing on the Effective Date and continuing for [***] such Co-Funding Target.

1.94 "Lead Party" shall mean Regeneron.

1.115 "Participating Party" shall mean Intellia.

2.2(b) There are instances where certain provisions of this Agreement only apply to Regeneron Co-Funding Products and not to Intellia Co-Funding Products and where such provisions were already set forth in the Collaboration Agreement with respect to Regeneron Products. In such cases, this Agreement incorporates by reference the applicable terms of the Collaboration Agreement, except that references to Regeneron Products in the applicable terms of the Collaboration Agreement shall be deemed to refer to Regeneron Co-Funding Products and references to the Collaboration Agreement in the applicable terms of the Collaboration Agreement shall be deemed to refer to this Agreement.

2.4(b)(viii) [Intentionally Omitted]

2.9 [Intentionally Omitted]

3.1 Development of Co-Funding Products. Subject to the terms of this Agreement, the Lead Party shall undertake, and in accordance with Section 3.2 with respect to a Regeneron Co-Funding Product the Parties shall jointly undertake, Development activities with respect to Co-Funding Products unless otherwise mutually agreed to in the Global Development Plan, and such Development activities shall be under the general direction and oversight of the JDC and JSC. [***]. Except as set forth in Section 3.2 with respect to a Regeneron Co-Funding Product or

otherwise agreed to by the Parties in writing or explicitly set forth in this Agreement, the JSC will assign responsibility for conducting all Development activities for a Co-Funding Product to the Lead Party. For clarity, with respect to a given Regeneron Product that constitutes a Co-Funding Product under this Agreement, the diligence obligations of Regeneron to develop and commercialize such Regeneron Product in Sections 4.4(d) and 6.1(a) of the Collaboration Agreement shall be superseded (from and after the Effective Date of this Agreement) by Regeneron's diligence obligations as a Lead Party for such Co-Funding Product under this Agreement, [***].

3.2 Existing Product R&D Programs and Associated Product R&D Plans.

(a) [Intentionally Omitted]

(b) The Participating Party may terminate this Agreement with respect to the Co-Funding Target and all Co-Funding Products Directed to such Co-Funding Target [***]. Upon such termination, the Regeneron Option exercised in conjunction with this Agreement shall no longer constitute one of the Regeneron Options exercised by Regeneron under Section 5.1 of the Collaboration Agreement. For clarity, each Party shall be responsible for the costs incurred under this Agreement through the date of termination in accordance with their respective Co-Funding Percentages.

3.3 New Product R&D Programs and Associated Product R&D Plans. In the event Regeneron exercises the Exercised Option to an Intellia Liver Target and Regeneron is the Lead Party for such Target, upon Regeneron's written request, Intellia shall perform certain activities for Regeneron under the Global Development Plan for such Regeneron Co-Funding Product, if Intellia has agreed to perform similar types of activities for Regeneron under a Product R&D Program and an associated Product R&D Plan for a Regeneron Product under the Collaboration Agreement (e.g., guide RNA and repair template design, optimization, and in vitro validation; in vitro functional assays; and development of non-viral systems for liver delivery; and the generation of CRISPR-Cas Materials and nanoparticle formulations for in-vivo proof of concept studies). [***].

3.4 Transition of Research and Development Activities for Regeneron Co-Funding Products that were formerly Intellia Liver Products. If the Co-Funding Target constitutes an Intellia Liver Target for which Regeneron is the Lead Party, Intellia shall, as promptly as reasonably practicable, [***]. The costs incurred by Intellia in the conduct of transition activities conducted pursuant to this Section 3.4 in accordance with the plan and cost estimate provided by Intellia pursuant to the previous sentence shall be treated as Development Costs and shared by the Parties in accordance with their respective Co-Funding Percentages.

3.5 Transition of Patent Prosecution Responsibilities. After Regeneron's exercise of the Exercised Option for an Intellia Liver Product Directed to an Intellia Liver Target for which Regeneron is designated as the Lead Party, Intellia shall, as promptly as reasonably practicable, transfer all Patent prosecution and maintenance responsibilities for Intellia Liver Product Inventions to Regeneron, including transferring all files related to the prosecution and maintenance

of such Patents to Regeneron and at the request of Regeneron, make appropriate personnel available to Regeneron to answer such reasonable questions as Regeneron may have in connection with the prosecution and maintenance of such Patents.

3.6(b) [Intentionally Omitted]

3.8 Intellia Technical Support Related to the Development of Regeneron Co-Funding Products. With respect to Regeneron Co-Funding Products, Section 6.1(b) of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). Costs incurred by Intellia in the conduct of activities conducted pursuant to this Section 3.8 shared by the Parties in accordance with their respective Co-Funding Percentages and shall be treated as Other Shared Expenses.

5.1(b)(ii) Regeneron shall be responsible for all communications with Regulatory Authorities in connection with Regeneron Co-Funding Products, with Intellia's support and input (which may include preparation by Intellia of [***]), which support and input shall be provided by Intellia upon reasonable request by Regeneron; provided that, in connection with such support prior to commencing such support, [***]. Costs incurred by Intellia in the conduct of the assistance contemplated by the previous sentence shall constitute Development Costs and shall be shared by the Parties in accordance with their respective Co-Funding Percentages.

5.1(c) With respect to Regeneron Co-Funding Products that were formerly Intellia Liver Products, Intellia shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of Regeneron, or otherwise to allow Regeneron to Develop and Commercialize Regeneron Co-Funding Products as set forth in this Agreement.

6.3 [Intentionally Omitted]

6.4 In the event that either (a) the use, practice or exercise by Regeneron (or any of its Affiliates or sublicensees) of any Intellia Intellectual Property in accordance with the licenses expressly granted to Regeneron in accordance with this Agreement or (b) the research, development, making, having made, use, sale, offering for sale, or import by Regeneron (or any of its Affiliates or sublicensees) of a Regeneron Co-Funding Product [***] for use in the Field, pursuant to, and in accordance with, this Agreement, would infringe or misappropriate any Patent Right which is first Controlled by Intellia or its Affiliates after the IP Term and which is not covered by the license grant in Section 6.1, Intellia shall grant, and hereby grants, to Regeneron a non-exclusive, royalty-free, worldwide, sublicensable in multiple tiers (in accordance with Section 7.2(c)) license under such Patent Right solely as necessary to (i) use, practice and exercise the Intellia Intellectual Property in accordance with the licenses expressly granted to Regeneron in accordance with this Agreement and (ii) research, develop, make, have made, use, sale, offer for sale, and import Regeneron Co-Funding Products for use in the Field in accordance with this Agreement, and solely for such purpose. The foregoing license under this Section 6.4 shall automatically terminate on a Regeneron Co-Funding Target-by-Regeneron Co-Funding Target

basis (and with respect to all Regeneron Co-Funding Products Directed to such Co-Funding Target) simultaneous with the termination of the license under Section 6.1 with respect to such Regeneron Co-Funding Product. [***].

7.2(c)(ii) [***].

7.3(d) [***].

7.4(b) With respect to Regeneron Co-Funding Products, the second sentence of Section 7.4(a) and Section 7.4(b) of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and any payments made by Regeneron in accordance Section 7.4(a) of the Collaboration Agreement shall be considered Third Party License Payments.

7.11 Ongoing Technology Update and Transfer Obligations. With respect to Regeneron Co-Funding Products, Section 7.11 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b). Costs incurred by Intellia in the performance of activities conducted pursuant to clause (c) of Section 7.11 of the Collaboration Agreement shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses.

7.12 [Intentionally Omitted]

8.1 Non-GMP Manufacture of Co-Funding Products. With respect to Regeneron Co-Funding Products, Section 8.1 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

8.2 With respect to a Regeneron Co-Funding Product that is Directed to a Co-Funding Target that was an Intellia Liver Target to which Regeneron exercised the Exercised Option (for which there is no Product R&D Program), Intellia shall manufacture (or have manufactured) the quantities of Co-Funding Products (including its components) that are necessary to perform the pre-clinical activities under the Global Development Plan and Section 8.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), except that the references to the Product R&D Program shall be deemed to refer to the Global Development Plan. [***].

8.3(b) With respect to a Regeneron Co-Funding Product, the second and third sentences of Section 8.3 of the Collaboration Agreement are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b).

8.4 Manufacturing Process Technology Transfer. With respect to Regeneron Co-Funding Products, [***].

9.1 Reimbursement for Past Expenses. Within [***] after the Effective Date of this Agreement, the Party that exercised the Exercised Option, as applicable, shall pay to the other Party an amount equal to [***].

9.13 [***]

9.14 Treatment of Certain Payments for Sharing of Profits and Development Costs for Regeneron Co-Funding Products.

(a) With respect to Regeneron Co-Funding Products, [***] the following amounts:

(i) [***]; and

(ii) [***].

(b) [***].

10.12(b) In the event that Regeneron is not fully able to enjoy any rights granted Regeneron under this Article 10 as a result of the provisions of this Section 10.11, then Intellia shall use diligent efforts to afford and allow Regeneron to exercise and enjoy such rights to the maximum extent possible under the applicable Third Party agreement (but Intellia shall not be required to amend or otherwise modify any such agreement, or make any payments to such Third Party), [***].

12.2 Additional Representations, Warranties and Covenants of the Parties.

(a) Except as set forth on Schedule 12.2(a)(1), Intellia additionally hereby represents and warrants to Regeneron, as modified by any exceptions to such representations and warranties applied *mutatis mutandis* to the subject matter of the Regeneron Option as set forth in the Option Package for the Co-Funding Target and Co-Funding Products, that as of the Option Exercise Date:

(i) There are no claims, judgments or settlements against or owed by Intellia (or any of its Affiliates) and no pending or, to Intellia's knowledge, threatened (in writing) claims or litigation, in each case, to which Intellia (or its Affiliates, or, to its or their knowledge, any of the counterparties to the Option Exercise Intellia Existing Third Party Agreements) is a party or threatened (in writing) party relating to the Intellia Intellectual Property or otherwise challenging Intellia's ownership or control of the Intellia Intellectual Property (such Intellia Intellectual Property, the "CFP Intellia IP");

(ii) Schedule 12.2(a)(1)(ii)(A) sets forth a true, correct and complete list of Patent Rights within the CFP Intellia IP existing as of the Option Exercise Date, (the "CFP Intellia Patent Rights"). To the knowledge of the individuals listed on Schedule

12.2(a)(1)(ii)(B) [***], the CFP Intellia Patent Rights exist and are not invalid or unenforceable, in whole or in part;

(iii) Intellia solely owns all CFP Intellia IP, except for such CFP Intellia IP that Intellia Controls pursuant to the Option Exercise Intellia Existing Third Party Agreements, and Intellia Controls all of the CFP Intellia Patent Rights;

(iv) Schedule 12.2(a)(1)(iv) sets forth a true, correct and complete list of all agreements with Third Parties pursuant to which Intellia has in-licensed, or otherwise obtained rights to, any Intellectual Property related to activities hereunder, including CRISPR-Cas, Targets, delivery technologies and CPs (the "Option Exercise Intellia Existing Third Party Agreements");

(v) Intellia is not aware of any claim made in writing against it asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of the CFP Intellia Patent Rights;

(vi) Neither Intellia nor any of its Affiliates is or has been a party to any agreement with the U.S. federal government or an agency thereof pursuant to which the U.S. federal government or such agency provided funding for the development of the CFP Intellia IP;

(vii) Neither Intellia nor any of its Affiliates has received any written notification from a Third Party that the use of any CFP Intellia IP infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party;

(viii) The CFP Intellia IP is not subject to any liens or encumbrances or other grants in favor of any Third Party that conflicts with the rights or licenses granted to Regeneron under this Agreement;

(ix) To the knowledge of the individuals listed on Schedule 12.2(a)(1)(ix) (without any duty to inquire), the conception, discovery, development or reduction to practice of CFP Intellia IP has not constituted or involved misappropriation of Intellectual Property or rights of any Person; and

(x) Intellia has a right and license to use the Patent Rights that are licensed to Intellia (directly or indirectly) under Option Exercise Intellia Existing Third Party Agreements on a worldwide basis, and Intellia is granting a sublicense to such Patent Rights to Regeneron for use on a worldwide basis, in each case, with respect to the foregoing, solely with respect to the Co-Funding Products hereunder;

(b) [Intentionally Omitted]

12.3(d) Covenants.

(i) With respect to the Regeneron Co-Funding Products under this Agreement, [***].

(ii) Section 12.4 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), except that any references to the Intellia Existing Third Party Agreements shall be deemed to refer to the Option Exercise Intellia Existing Third Party Agreements.

SUB-ANNEX 1(C):

Intellia Co-Funding Target

1.17 "Co-Funding Product" shall mean each Intellia Co-Funding Product that is Directed to the Co-Funding Target.

1.27 [Intentionally Omitted]

1.38

4. [Intentionally Omitted]

1.44 "Exercised Option" shall mean the Intellia Option exercised by Intellia under Section 5.2(c) of the Collaboration Agreement, in accordance with the Collaboration Agreement, for the Target set forth on Schedule 1.44 of this Agreement.

1.89 [Intentionally Omitted]

1.94 "Lead Party" shall mean Intellia.

1.115 "Participating Party" shall mean Regeneron.

2.2(b) [Intentionally Omitted]

2.4(b)(viii) [***];

2.9 [***].

3.1 Development of Co-Funding Products. Subject to the terms of this Agreement, the Lead Party shall undertake, Development activities with respect to Co-Funding Products unless otherwise mutually agreed to in the Global Development Plan, and such Development activities shall be under the general direction and oversight of the JDC and JSC. [***]. Except as otherwise agreed to by the Parties in writing or explicitly set forth in this Agreement, the JSC will assign responsibility for conducting all Development activities for a Co-Funding Product to the Lead Party.

3.2 Existing Product R&D Programs and Associated Product R&D Plans.

(a) [Intentionally Omitted]

(b) The Participating Party may terminate this Agreement with respect to the Co-Funding Target and all Co-Funding Products Directed to such Co-Funding Target [***]. Upon such termination, the Intellia Option exercised in conjunction with this Agreement shall no longer constitute one of the Intellia Options exercised by Intellia under Section 5.2 of the Collaboration

Agreement. For clarity, each Party shall be responsible for the costs incurred under this Agreement through the date of termination in accordance with their respective Co-Funding Percentages.

3.3 [Intentionally Omitted]

3.4 [Intentionally Omitted]

3.5 [Intentionally Omitted]

3.6(b) [Intentionally Omitted]

3.8 [Intentionally Omitted]

5.1(b)(ii) [Intentionally Omitted]

5.1(c) [Intentionally Omitted]

6.3 [***].

6.4 Subject to the terms and conditions of this Agreement (including Section 6.1 and Section 12.6), Regeneron shall grant, and hereby grants, to Intellia a non-exclusive, worldwide, sublicensable through multiple tiers (in accordance with Section 7.2(c), provided that such sublicense shall not require the prior written consent of Regeneron), royalty-free and fully paid-up (subject to Section 7.12) license under Patents Rights and Know-How Controlled by Regeneron solely to the extent necessary (and with respect to any Patent Rights, on a claim-by-claim basis) to use, practice and otherwise exploit the applicable Regeneron Contributed Technology [***] for the research, development, making, having made, using, selling, offering for sale and importing of Intellia Co-Funding Products.

7.2(c)(ii) [Intentionally Omitted].

7.3(d) To the extent that any milestones or royalties under a New Intellia Platform License are attributable to one or more Co-Funding Products (as opposed to amounts attributable to other products or activities) [***].

7.4(b) [Intentionally Omitted]

7.11 Ongoing Technology Update and Transfer Obligations. Without limiting the last sentence of Section 6.3, [***]. Costs incurred by Regeneron in the performance of activities conducted pursuant to clause (b)(ii) of this Section 7.11 shall be shared by the Parties in accordance with their respective Co-Funding Percentages and treated as Other Shared Expenses.

7.12 Regeneron Contributed IP. With respect to Co-Funding Products for which Intellia has a license to Regeneron Contributed IP pursuant to Section 6.3:

(a) Section 7.12 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and any payments made by Intellia to Regeneron in accordance with Section 7.12 of the Collaboration Agreement shall be considered Third Party License Payments hereunder and treated in accordance with Section 7.5 of this Agreement.

(b) In the event that any Regeneron Contributed IP (or other Intellectual Property licensed by Regeneron to Intellia hereunder) [***] with respect to the Co-Funding Products hereunder, (1) Regeneron will provide prompt written notice thereof to Intellia, and (2) unless Regeneron is already undertaking such efforts for itself and Intellia, Regeneron will provide reasonable assistance to Intellia in Intellia's efforts to obtain rights to such Intellectual Property Rights consistent with the rights (including scope) granted by Regeneron to Intellia under this Agreement pertaining to the Co-Funding Products hereunder.

8.1 Non-GMP Manufacture of Intellia Co-Funding Products. With respect to Intellia Co-Funding Products, Intellia will be responsible for the non-GMP Manufacture and supply of Intellia Co-Funding Products to support the research and pre-clinical development of Intellia Co-Funding Products.

8.2 Intellia shall manufacture (or have manufactured) the quantities of Co-Funding Products (including its components) that are necessary to perform the pre-clinical activities under the Global Development Plan and the first sentence of Section 8.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), except that the references to the Product R&D Program shall be deemed to refer to the Global Development Plan (or the Option Package for such Co-Funding Product prior to approval of such Global Development Plan). [***].

8.3(b) [Intentionally Omitted]

8.4 [Intentionally Omitted]

9.1 Reimbursement for Past Expenses. Within [***] after the Effective Date of this Agreement, Regeneron shall pay to Intellia an amount equal to [***].

9.13 [***]

(a) [***]; or

(b) [***]

9.14 Treatment of Certain Payments for Sharing of Profits and Development Costs for Intellia Co-Funding Products.

(a) With respect to Intellia Co-Funding Products, [***] the following amounts:

(i) [***]; and

(ii) [***].

(b) [***].

10.12(b) [Intentionally Omitted]

12.2 Additional Representations, Warranties and Covenants of the Parties.

(a) (i) Except as set forth on Schedule 12.2(a)(i), Intellia additionally hereby represents and warrants to Regeneron, as modified by any exceptions to such representations and warranties applied *mutatis mutandis* to the subject matter of the Regeneron Option as set forth in the Option Package for the Co-Funding Target and Co-Funding Products, that as of the Option Exercise Date:

(1) There are no claims, judgments or settlements against or owed by Intellia (or any of its Affiliates) and no pending or, to Intellia's knowledge, threatened (in writing) claims or litigation, in each case, to which Intellia (or its Affiliates, or, to its or their knowledge, any of the counterparties to the Option Exercise Intellia Existing Third Party Agreements) is a party or threatened (in writing) party relating to the Intellia Intellectual Property or otherwise challenging Intellia's ownership or control of the Intellia Intellectual Property (such Intellia Intellectual Property, the "CFP Intellia IP");

(2) Schedule 12.2(a)(i)(2)(A) sets forth a true, correct and complete list of Patent Rights within the CFP Intellia IP existing as of the Option Exercise Date, (the "CFP Intellia Patent Rights"). To the knowledge of the individuals listed on Schedule 12.2(a)(1)(ii)(B) [***], the CFP Intellia Patent Rights exist and are not invalid or unenforceable, in whole or in part;

(3) Intellia solely owns all CFP Intellia IP, except for such CFP Intellia IP that Intellia Controls pursuant to the Option Exercise Intellia Existing Third Party Agreements; and Intellia Controls all of the CFP Intellia Patent Rights;

(4) Schedule 12.2(a)(i)(4) sets forth a true, correct and complete list of all agreements with Third Parties pursuant to which Intellia has in-licensed, or otherwise obtained rights to, any Intellectual Property related to activities hereunder, including CRISPR-Cas, Targets, delivery technologies and CPs (the "Option Exercise Intellia Existing Third Party Agreements");

(5) Intellia is not aware of any claim made in writing against it asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of the CFP Intellia Patent Rights;

(6) Neither Intellia nor any of its Affiliates is or has been a party to any agreement with the U.S. federal government or an agency thereof pursuant to which the U.S. federal government or such agency provided funding for the development of the CFP Intellia IP;

(7) Neither Intellia nor any of its Affiliates has received any written notification from a Third Party that the use of any CFP Intellia IP infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party;

(8) The CFP Intellia IP is not subject to any liens or encumbrances or other grants in favor of any Third Party that conflicts with the rights or licenses granted to Regeneron under this Agreement;

(9) To the knowledge of the individuals listed on Schedule 12.2(a)(i)(9) [***], the conception, discovery, development or reduction to practice of CFP Intellia IP has not constituted or involved misappropriation of Intellectual Property or rights of any Person; and

(10) Intellia has a right and license to use the Patent Rights that are licensed to Intellia (directly or indirectly) under the Option Exercise Intellia Existing Third Party Agreements on a worldwide basis.

(ii) With respect to the agreements set forth on Schedule 12.2(a)(1)(iv) (as may be amended from time to time (the "Intellia Agreements"), Intellia hereby represents and warrants as of the Effective Date, and covenants during the Term, to Regeneron that:

(1) Sections 12.4(a)(i) and (ii) of the Collaboration Agreement (as applied *mutatis mutandis*) are hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), in each case, with respect to the foregoing, solely with respect to the Co-Funding Products except that any references to the Intellia Existing Third Party Agreements shall be deemed to refer to the Option Exercise Intellia Existing Third Party Agreements. [***]; and

(2) Intellia shall fulfill all of its material obligations, including its payment obligations, under the Option Exercise Intellia Existing Third Party Agreements, with respect to the Co-Funding Products under this Agreement.

12.3(d) [Intentionally Omitted]

SUB-ANNEX 1(D):

TTR

1.17 "Co-Funding Product" shall mean each Co-Funding Product that is Directed to the Initial Co/Co Target.

1.27 [Intentionally Omitted]

1.38

4. [***].

1.44 "Exercised Option" shall mean the Regeneron Option exercised by Regeneron under Section 5.1(e) of the Collaboration Agreement in accordance with the Collaboration Agreement, for the Initial Co/Co Target, as such term is defined in the Collaboration Agreement.

1.89 [Intentionally Omitted]

1.94 "Lead Party" shall mean Intellia.

1.115 "Participating Party" shall mean Regeneron.

2.2(b) [Intentionally Omitted]

2.4(b)(viii) [***];

2.9 [***].

3.1 Development of Co-Funding Products. Subject to the terms of this Agreement, the Lead Party shall undertake, Development activities with respect to Co-Funding Products unless otherwise mutually agreed to in the Global Development Plan, and such Development activities shall be under the general direction and oversight of the JDC and JSC. [***]. Except as otherwise agreed to by the Parties in writing or explicitly set forth in this Agreement, the JSC will assign responsibility for conducting all Development activities for a Co-Funding Product to the Lead Party.

3.2 [Intentionally Omitted]

3.3 [Intentionally Omitted]

3.4 [Intentionally Omitted]

3.5 [Intentionally Omitted]

3.6(b) Schedule 5.1(e)(iii) of the Collaboration Agreement shall be deemed to be the initial Global Development Plan for the Initial Co/Co Target until updated by Intellia and reviewed and approved by the JSC.

3.8 [Intentionally Omitted]

5.1(b)(ii) [Intentionally Omitted]

5.1(c) [Intentionally Omitted]

6.3 [***].

6.4 Subject to the terms and conditions of this Agreement (including Section 6.1 and Section 12.6), Regeneron shall grant, and hereby grants, to Intellia a non-exclusive, worldwide, sublicensable through multiple tiers (in accordance with Section 7.2(c)), provided that such sublicense shall not require the prior written consent of Regeneron), royalty-free and fully paid-up (subject to Section 7.12) license under Patents Rights and Know-How Controlled by Regeneron solely to the extent necessary (and with respect to any Patent Rights, on a claim-by-claim basis) to use, practice and otherwise exploit the applicable Regeneron Contributed Technology [***] for the research, development, making, having made, using, selling, offering for sale and importing of Intellia Co-Funding Products.

7.2(c)(ii) [Intentionally Omitted].

7.3(d) [***].

7.4(b) [Intentionally Omitted]

7.11 Ongoing Technology Update and Transfer Obligations. Without limiting the last sentence of Section 6.3, [***]. Costs incurred by Regeneron in the performance of activities conducted pursuant to clause (b)(ii) of this Section 7.11 [***].

7.12 Regeneron Contributed IP. With respect to Co-Funding Products for which Intellia has a license to Regeneron Contributed IP pursuant to Section 6.3:

(a) Section 7.12 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b) and [***].

(b) In the event that any Regeneron Contributed IP (or other Intellectual Property licensed by Regeneron to Intellia hereunder) is [***] with respect to the Co-Funding Products hereunder, (1) Regeneron will provide prompt written notice thereof to Intellia, and (2) unless Regeneron is already undertaking such efforts for itself and Intellia, Regeneron will provide reasonable assistance to Intellia in Intellia's efforts to obtain rights to such Intellectual Property Rights consistent with the rights (including scope) granted by Regeneron to Intellia under this Agreement pertaining to the Co-Funding Products hereunder.

8.1 Non-GMP Manufacture of Co-Funding Products. With respect to Intellia Co-Funding Products, Intellia will be responsible for the non-GMP Manufacture and supply of Intellia Co-Funding Products to support the research and pre-clinical development of Intellia Co-Funding Products.

8.2 Intellia shall manufacture (or have manufactured) the quantities of Co-Funding Products (including its components) that are necessary to perform the pre-clinical activities under the Global Development Plan and the first sentence of Section 8.2 of the Collaboration Agreement is hereby incorporated by reference into this Agreement in accordance with Section 2.2(b), except that the references to the Product R&D Program shall be deemed to refer to the Global Development Plan. [***].

8.3(b) [Intentionally Omitted]

8.4 [Intentionally Omitted]

9.1 Reimbursement for Past Expenses. [***]. The Lead Party provided to the Participating Party invoices totaling [***] to be paid by the Participating Party [***].

9.13 [***]. [***] Payments under this Agreement, and as between the [***].

9.14 Treatment of Certain Payments for Sharing of Profits and Development Costs for Co-Funding Products. With respect to Intellia Co-Funding Products, in the event that Intellia (or its Affiliate or sublicensee) is required to make any upfront, annual or other license fees, milestone or royalty payments to a Third Party as a result of a license (or other right) granted to Intellia (or its Affiliate or sublicensee) by such Third Party under such Third Party's Intellectual Property or otherwise in connection with any settlement with such Third Party [***].

12.2 Additional Representations, Warranties and Covenants of the Parties.

(a) [Intentionally Omitted]

(b)

(i) [***].

(ii) Intellia shall fulfill all of its material obligations, including its payment obligations, under the Intellia Existing Third Party Agreements, with respect to the Intellia Co-Funding Products under this Agreement.

12.3(d) [Intentionally Omitted]

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, John M. Leonard, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intellia Therapeutics, 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: October 31, 2018

/s/ John M. Leonard
John M. Leonard, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Glenn Goddard, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intellia Therapeutics, 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: October 31, 2018

/s/ Glenn Goddard

Glenn Goddard
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CEO AND CFO PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Quarterly Report on Form 10-Q of Intellia Therapeutics, Inc. (the "Company") for the period ended September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, John M. Leonard, M.D., President and Chief Executive Officer of the Company, and Glenn Goddard, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. (section) 1350, as adopted pursuant to (section) 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(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 results of operations of the Company.

Dated: October 31, 2018

/s/ John M. Leonard
John M. Leonard, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Glenn Goddard
Glenn Goddard
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)