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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

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 001-37687

EDITAS MEDICINE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**46-4097528**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11 Hurley Street Cambridge, Massachusetts	**02141**
(Address of principal executive offices)	**(Zip Code)**

(617) 401-9000
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	EDIT	The Nasdaq Stock Market LLC

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

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

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

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

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

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

The number of shares of Common Stock outstanding as of October 30, 2020 was 62,334,218.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

Editas Medicine, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(amounts in thousands, except share and per share data)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 279,576	$ 238,183
Marketable securities	215,729	218,957
Accounts receivable	1,055	418
Prepaid expenses and other current assets	10,467	6,286
Total current assets	506,827	463,844
Marketable securities	45,986	—
Property and equipment, net	14,069	10,887
Right-of-use assets	26,398	28,761
Restricted cash and other non-current assets	3,877	5,393
Total assets	$ 597,157	$ 508,885
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,158	$ 5,843
Accrued expenses	20,307	22,120
Deferred revenue, current	19,874	23,514
Operating lease liabilities	6,342	5,804
Other current liabilities	3,135	2,682
Total current liabilities	54,816	59,963
Operating lease liabilities, net of current portion	20,368	23,277
Deferred revenue, net of current portion	80,821	163,207
Other non-current liabilities	—	1
Total liabilities	156,005	246,448
Stockholders' equity		
Preferred stock, $0.0001 par value per share: 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.0001 par value per share: 195,000,000 shares authorized; 62,331,700 and 54,533,798 shares issued, and 62,187,700 and 54,355,798 shares outstanding at September 30, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	1,043,892	811,546
Accumulated other comprehensive (loss) income	(48)	107
Accumulated deficit	(602,698)	(549,221)
Total stockholders' equity	441,152	262,437
Total liabilities and stockholders' equity	$ 597,157	$ 508,885

The accompanying notes are an integral part of the condensed consolidated financial statements.

Editas Medicine, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(amounts in thousands, except per share and share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration and other research and development revenues	$ 62,841	$ 3,848	$ 79,313	$ 8,247
Operating expenses:				
Research and development	33,916	22,702	96,492	62,109
General and administrative	19,936	15,734	51,789	47,638
Total operating expenses	53,852	38,436	148,281	109,747
Operating income (loss)	8,989	(34,588)	(68,968)	(101,500)
Other (expense) income, net:				
Other (expense) income, net	(1,396)	(33)	13,114	(144)
Interest income, net	226	1,680	2,377	5,668
Total other (expense) income, net	(1,170)	1,647	15,491	5,524
Net income (loss)	$ 7,819	$ (32,941)	$ (53,477)	$ (95,976)
Net income (loss) per share, basic	$ 0.13	$ (0.66)	$ (0.93)	$ (1.95)
Net income (loss) per share, diluted	$ 0.12	$ (0.66)	$ (0.93)	$ (1.95)
Weighted-average common shares outstanding, basic	62,144,118	49,820,455	57,377,581	49,246,684
Weighted-average common shares outstanding, diluted	62,697,173	49,820,455	57,377,581	49,246,684

The accompanying notes are an integral part of the condensed consolidated financial statements.

Editas Medicine, Inc.
Condensed Consolidated Statements of Comprehensive Income (Loss)
(unaudited)
(amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 7,819	$ (32,941)	$ (53,477)	$ (95,976)
Other comprehensive income (loss):				
Unrealized (loss) gain on marketable debt securities	(231)	(6)	(155)	68
Comprehensive income (loss)	$ 7,588	$ (32,947)	$ (53,632)	$ (95,908)

The accompanying notes are an integral part of the condensed consolidated financial statements.

Editas Medicine, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(amounts in thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Other Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2019	54,355,798	$ 5	$ 811,546	$ 107	$ (549,221)	$ 262,437
Exercise of stock options	233,208	—	3,047	—	—	3,047
Vesting of restricted common stock awards	213,393	—	—	—	—	—
Stock-based compensation expense	—	—	6,220	—	—	6,220
Unrealized gain on marketable debt securities	—	—	—	587	—	587
Net loss	—	—	—	—	(37,724)	(37,724)
Balance at March 31, 2020	54,802,399	$ 5	$ 820,813	$ 694	$ (586,945)	$ 234,567
Exercise of stock options	355,812	—	6,839	—	—	6,839
Issuance of common stock for public offering	6,900,000	1	203,681	—	—	203,682
Stock-based compensation expense	—	—	5,417	—	—	5,417
Vesting of restricted common stock awards	30,194	—	—	—	—	—
Purchase of common stock under benefit plans	15,244	—	350	—	—	350
Unrealized loss on marketable debt securities	—	—	—	(511)	—	(511)
Net loss	—	—	—	—	(23,572)	(23,572)
Balance at June 30, 2020	62,103,649	$ 6	$ 1,037,100	$ 183	$ (610,517)	$ 426,772
Exercise of stock options	48,312	—	947	—	—	947
Stock-based compensation expense	—	—	5,845	—	—	5,845
Vesting of restricted common stock awards	35,739	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(231)	—	(231)
Net income	—	—	—	—	7,819	7,819
Balance at September 30, 2020	62,187,700	$ 6	$ 1,043,892	$ (48)	$ (602,698)	$ 441,152

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Other Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance at December 31, 2018	48,758,951	$ 5	$ 652,464	$ (29)	$ (416,278)	$ 236,162
Cumulative effect adjustment for adoption of new accounting guidance	—	—	—	—	803	803
Exercise of stock options	146,171	—	1,533	—	—	1,533
Vesting of restricted common stock awards	18,000	—		—	—	—
Stock-based compensation expense	—	—	7,855	—	—	7,855
Unrealized gain on marketable debt securities	—	—	—	58	—	58
Net loss	—	—	—	—	(29,249)	(29,249)
Balance at March 31, 2019	48,923,122	$ 5	$ 661,852	$ 29	$ (444,724)	$ 217,162
Exercise of stock options	277,259	—	2,894	—	—	2,894
Vesting of restricted common stock awards	24,486	—	410	—	—	410
Purchase of common stock under benefit plan	16,226	—	283	—	—	283
Stock-based compensation expense	—	—	6,083	—	—	6,083
Unrealized gain on marketable debt securities	—	—	—	16	—	16
Net loss	—	—	—	—	(33,786)	(33,786)
Balance at June 30, 2019	49,241,093	$ 5	$ 671,522	$ 45	$ (478,510)	$ 193,062
Exercise of stock options	78,804	—	1,329	—	—	1,329
Vesting of restricted common stock awards	34,566	—	—	—	—	—
Stock-based compensation expense	—	—	6,559	—	—	6,559
Issuance of common stock from public offering, net of issuance costs of $0.1 million	1,721,735	—	41,987	—	—	41,987
Unrealized loss on marketable debt securities	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	(32,941)	(32,941)
Balance at September 30, 2019	51,076,198	$ 5	$ 721,397	$ 39	$ (511,451)	$ 209,990

The accompanying notes are an integral part of the condensed consolidated financial statements.

Editas Medicine, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(amounts in thousands)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flow from operating activities		
Net loss	$ (53,477)	$ (95,976)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	17,483	20,907
Depreciation	2,776	2,048
Unrealized gain on corporate equity securities	(13,109)	—
Other non-cash items, net	(285)	(2,427)
Changes in operating assets and liabilities:		
Accounts receivable	(637)	(281)
Prepaid expenses and other current assets	(4,181)	263
Right-of-use assets	2,363	1,780
Other non-current assets	106	(14)
Accounts payable	(447)	1,005
Accrued expenses	(2,391)	(4,491)
Deferred revenue	(86,026)	(2,928)
Operating lease liabilities	(2,371)	(2,107)
Other current and non-current liabilities	453	528
Net cash used in operating activities	(139,743)	(81,693)
Cash flow from investing activities		
Purchases of property and equipment	(5,786)	(4,476)
Proceeds from the sale of equipment	21	36
Purchases of marketable securities	(300,363)	(305,126)
Proceeds from maturities of marketable securities	274,500	314,000
Net cash (used in) provided by investing activities	(31,628)	4,434
Cash flow from financing activities		
Proceeds from offering of common stock, net of issuance costs	203,839	41,216
Proceeds from exercise of stock options	10,833	5,756
Issuance of common stock under benefit plans	350	283
Net cash provided by financing activities	215,022	47,255
Net increase (decrease) in cash, cash equivalents, and restricted cash	43,651	(30,004)
Cash, cash equivalents, and restricted cash, beginning of period	239,802	136,395
Cash, cash equivalents, and restricted cash, end of period	$ 283,453	$ 106,391
Supplemental disclosure of cash and non-cash activities:		
Fixed asset additions included in accounts payable and accrued expenses	$ 910	$ 772
Receivable of proceeds from offering of common stock	—	756
Cash paid in connection with operating lease liabilities	7,757	4,604
Offering costs included in accounts payable and accrued expenses	158	15
Right-of-use assets obtained in exchange of operating lease obligations	—	19,461

The accompanying notes are an integral part of the condensed consolidated financial statements.

Editas Medicine, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

Editas Medicine, Inc. (the "Company") is a leading, clinical stage genome editing company dedicated to developing potentially transformative genomic medicines to treat a broad range of serious diseases. The Company was incorporated in the state of Delaware in September 2013. Its principal offices are in Cambridge, Massachusetts.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and raising capital. The Company has primarily financed its operations through various equity financings, payments received under a research collaboration with Juno Therapeutics, Inc., a wholly-owned subsidiary of the Bristol-Myers Squibb Company ("Juno Therapeutics"), and payments received under a strategic alliance with Allergan Pharmaceuticals International Limited (which was acquired by AbbVie, Inc. in May 2020 and is referred to together with its affiliates as "Allergan"). In August 2020, the collaboration with Allergan was terminated.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations and ability to transition from pilot-scale manufacturing to large-scale production of products.

Liquidity

In May 2020, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), under which the Company from time to time can issue and sell shares of its common stock through Cowen in at-the-market offerings for aggregate gross sale proceeds of up to $150.0 million (the "ATM Facility"). As of September 30, 2020, the Company has not sold any shares of its common stock under the ATM Facility. In June 2020, the Company completed a public offering whereby the Company sold 6,900,000 shares of its common stock, inclusive of 900,000 shares of common stock sold by the Company pursuant to the full exercise of an option granted to the underwriters in connection with the offering and received net proceeds of approximately $203.7 million. As of September 30, 2020, the Company has raised an aggregate of $648.7 million in net proceeds through the sale of shares of its common stock in public offerings and at-the-market offerings.

The Company has incurred annual net operating losses in every year since its inception. The Company expects that its existing cash, cash equivalents and marketable securities at September 30, 2020 and anticipated interest income will enable it to fund its operating expenses and capital expenditure requirements into 2023. The Company had an accumulated deficit of $602.7 million at September 30, 2020, and will require substantial additional capital to fund its operations. The Company has never generated any product revenue. There can be no assurance that the Company will be able to obtain additional debt or equity financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The condensed 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 (the "SEC"). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed 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 fiscal year ended December 31, 2019 (the "Annual Report").

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Editas Securities Corporation. All intercompany transactions and balances of the subsidiary have been eliminated in consolidation. 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 three months ended September 30, 2020 and 2019 are referred to as the third quarter of 2020 and 2019, respectively. 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.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of significant accounting policies," to the consolidated financial statements included in the Annual Report. There have been no material changes to the significant accounting policies previously disclosed in the Annual Report, other than as noted below.

Corporate Equity Securities

The Company classifies investments in equity securities that have a readily determinable fair value as marketable securities in the Company's condensed consolidated balance sheets. The Company's marketable securities are stated at fair value. Typically, the fair value of these securities is based on a quoted price for an identical equity security. If the equity security has a restriction that is determined to be an attribute of the security that would transfer to a market participant, the fair value of the security is measured based on the quoted price for an otherwise identical unrestricted equity security, adjusted for the effect of the restriction. The adjustment reflects the discount that a market participant would demand for the risk relating to the inability to dispose of the security for a specified period of time. That adjustment is based on the nature and duration of the restriction and the limitations imposed by the restriction to a buyer. The Company records changes in the fair value of its equity securities in "Other Income (Expense), net" in the Company's condensed consolidated statement of operations.

Recent Accounting Pronouncements – Recently Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Statement Update ("ASU") 2016-13, *Financial Instruments-Credit Losses* ("ASU 2016-13") which was clarified and amended by the issuances of ASUs 2018-19, 2019-04, 2019-05 and 2019-11 in November 2018, April 2019, May 2019 and November 2019, respectively. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis to be measured using an expected-loss model, replacing the current incurred-loss model, and recorded through an allowance for credit losses which is a valuation account that is deducted from the amortized cost basis of the financial asset. ASU 2016-13 requires evaluation of credit loss based on historical experience, current conditions and reasonable and supportable forecasts. The Company's estimate of expected credit losses includes a measure of the expected risk of credit loss even if the risk is remote. When assessing financial assets for credit losses, the Company pools financial assets with similar risk characteristics and performs a collective evaluation. However, the Company is not required to measure expected credit losses in which historical credit loss information adjusted for

current conditions and reasonable and supportable forecasts results in an expectation that nonpayment of the amortized cost basis is zero. At each reporting date, the Company will record an allowance for credit losses and reports it as credit loss expense which is included in "Other income (expense), net" in the Company's condensed consolidated statement of operations. However subsequent increases or decreases in the fair value of available-for-sale securities that do not result in recognition or reversal of an allowance for credit loss or write-down will continue to be recorded in other comprehensive loss. The Company adopted the new standard and the related amendments on January 1, 2020 using a modified retrospective approach. The modified retrospective approach requires the Company to record a one-time adjustment to opening accumulated deficit as of the effective date. At adoption, the Company concluded that there are no indicators of credit loss with respect to its available-for-sale debt securities which consist of U.S Treasury securities and government-agency bonds. The Company therefore did not record an allowance for credit losses or doubtful accounts upon adoption or during the first quarter of 2020. The adoption of ASU 2016-13 had no impact on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal Use Software: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 was effective on January 1, 2020. The Company adopted ASU 2018-15 using the prospective transition approach, which allows the Company to change the accounting method without restating prior periods or recording cumulative adjustments. The adoption of ASU 2018-15 did not have a material impact on the Company's condensed consolidated financial statements.

In 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which eliminates, adds, and modifies the disclosure requirements for fair value measurements. ASU 2018-13 was effective on January 1, 2020. The adoption of ASU 2018-13 results in additional disclosures related to the Company's assets and liabilities that are valued based on Level 3 inputs and transfers between Level 1 and Level 2 fair value measurements. The adoption of ASU 2018-13 did not have a material impact on the Company's financial statement footnote disclosures.

3. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following at September 30, 2020 (in thousands):

September 30, 2020	Amortized Cost	Allowance for Credit Losses	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents and marketable securities:					
Money market funds	$ 259,081	$ —	$ —	$ —	$ 259,081
U.S. Treasuries	165,518	—	20	(6)	165,532
Government agency securities	49,214	—	—	(20)	49,194
Corporate equity securities	3,667	—	13,109	—	16,776
Commercial paper	25,928	—	—	(4)	25,924
Corporate notes/bonds	24,823	—	—	(39)	24,784
Total	$ 528,231	$ —	$ 13,129	$ (69)	$ 541,291

Cash equivalents and marketable securities consisted of the following at December 31, 2019 (in thousands):

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents and marketable securities:				
Money market funds	$ 230,201	$ —	$ —	$ 230,201
U.S. Treasuries	71,348	20	—	71,368
Government agency securities	155,484	87	—	155,571
Equity securities included in other non-current assets:				
Corporate equity securities	3,667	—	—	3,667
Total	$ 460,700	$ 107	$ —	$ 460,807

As of September 30, 2020, the Company did not hold any marketable securities that had been in an unrealized loss position for more than twelve months. Furthermore, the Company has determined that there were no material changes in the credit risk of the debt securities. As of September 30, 2020, the Company holds 21 securities with an aggregate fair value of $46.0 million that had remaining maturities between one and two years.

There were no realized gains or losses on available-for-sale securities during the nine months ended September 30, 2020 or 2019.

4. Fair Value Measurements

Assets measured at fair value on a recurring basis as of September 30, 2020 were as follows (in thousands):

Financial Assets	September 30, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 259,081	$ 259,081	$ —	$ —
Marketable securities:				
U.S. Treasuries	165,532	165,532	—	—
Government agency securities	49,194	—	49,194	—
Commercial paper	25,924	—	25,924	—
Corporate equity securities	16,776	16,776	—	—
Corporate bonds	24,784	—	24,784	—
Restricted cash and other non-current assets:				
Money market funds	3,877	3,877	—	—
Total financial assets	$ 545,168	$ 445,266	$ 99,902	$ —

Assets measured at fair value on a recurring basis as of December 31, 2019 were as follows (in thousands):

Financial Assets	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Money market funds	$ 230,201	$ 230,201	$ —	$ —
U.S. Treasuries	7,982	7,982	—	—
Marketable securities:				
U.S. Treasuries	63,386	63,386	—	—
Government agency securities	155,571	155,571	—	—
Restricted cash and other non-current assets:				
Corporate equity securities	3,667	—	3,667	—
Money market funds	1,619	1,619	—	—
Total financial assets	$ 462,426	$ 458,759	$ 3,667	$ —

At September 30, 2020, the Company held an investment in Beam Therapeutics Inc. ("Beam Therapeutics") consisting of shares of Beam Therapeutics' common stock. Prior to Beam Therapeutics' initial public offering in February 2020, the Company valued such investment based on the cost of the equity securities adjusted for any observable market transactions. Following the initial public offering, the equity securities have a readily determinable fair value, and are included in marketable securities on the condensed consolidated balance sheet. During the three and nine months ended September 30, 2020, the Company recorded unrealized losses of $1.4 million and unrealized gains of $16.8 million, respectively in other income (expense), net on the consolidated statements of operations. The Company sold this investment in October 2020, resulting in a realized gain of $16.3 million.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of	
	September 30, 2020	December 31, 2019
Employee related expenses	$ 6,634	$ 4,971
Professional service expenses	5,037	674
Process and platform development expenses	5,019	735
Intellectual property and patent related fees	2,653	3,725
Other expenses	964	599
Sublicensing expenses	—	11,416
Total accrued expenses	$ 20,307	$ 22,120

6. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	As of	
	September 30, 2020	December 31, 2019
Laboratory equipment	$ 17,483	$ 14,571
Leasehold improvements	4,990	1,042
Computer equipment	858	858
Construction-in-progress	300	1,336
Furniture and office equipment	239	166
Software	118	118
Total property and equipment	23,988	18,091
Less: accumulated depreciation	(9,919)	(7,204)
Property and equipment, net	$ 14,069	$ 10,887

7. Commitments and Contingencies

The Company is a party to a number of license agreements under which the Company licenses patents, patent applications and other intellectual property from third parties. As such, the Company is obligated to pay licensors for various costs including upfront licenses fees, annual license fees, certain licensor expense reimbursements, success payments, research funding payments, and milestones triggerable upon certain development, regulatory, and commercial events as well as royalties on future products. These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties. The terms and conditions as well as the accounting analysis for the Company's significant commitments and contingencies are described in Note 8, "Commitments and Contingencies" to the consolidated financial statements included in the Annual Report. There have been no material changes to the terms and conditions, or the accounting conclusions previously disclosed in the Annual Report.

Licensor Expense Reimbursement

The Company is obligated to reimburse The Broad Institute, Inc. ("Broad") and the President and Fellows of Harvard College ("Harvard") for expenses incurred by each of them associated with the prosecution and maintenance of the patent rights that the Company licenses from them pursuant to the license agreement by and among the Company, Broad and Harvard, including the interference and opposition proceedings involving patents licensed to the Company under the license agreement, and other license agreements between the Company and Broad. As such, the Company anticipates that it has a substantial commitment in connection with these proceedings until such time as these proceedings have been resolved, but the amount of such commitment is not determinable. The Company incurred an aggregate of $2.6 million and $9.3 million in expense during the three and nine months ended September 30, 2020, respectively, for such reimbursement. The Company incurred an aggregate of $3.1 million and $10.1 million in expense during the three and nine months ended September 30, 2019, respectively, for such reimbursement.

8. Collaboration and Profit-Sharing Agreements

The Company has entered into multiple collaborations, out-licenses and strategic alliances with third parties that typically involve payments to or from the Company, including up-front payments, payments for research and development services, option payments, milestone payments and royalty payments to or from the Company. The terms and conditions as well as the accounting analysis for the Company's significant collaborations, out-licenses and strategic alliances are described in Note 9, "Collaboration and Profit-Sharing Agreements" to the consolidated financial statements included in the Annual Report. There have been no material changes to the terms and conditions, or the accounting conclusions previously disclosed in the Annual Report, other than as noted below.

Allergan Pharmaceuticals Strategic Alliance and Profit-Sharing Agreement

Termination Agreements

On August 5, 2020, the Company and Allergan agreed to terminate the strategic alliance and option agreement (the "Collaboration Agreement") that was entered into in May 2017 and the profit-sharing arrangement (together with the Collaboration Agreement, the "Initial Agreements") to equally split U.S profit and losses of EDIT-101, an experimental medicine for Leber congenital amaurosis 10 ("LCA10") that was originally licensed to Allergan under the Collaboration Agreement (the "Termination Agreement"). In addition, in connection with the termination, the Company entered into a transition services agreement with Allergan (together with the Termination Agreement, the "Termination Agreements"), primarily to facilitate the transfer of EDIT-101 back to the Company.

Pursuant to the Termination Agreements, the Company has regained full global rights to research, develop, manufacture, and commercialize its ocular medicines, including EDIT-101. Allergan has no further obligations pursuant to the initial agreements, all unexercised options and contingent payments contemplated under the initial agreements have terminated, which includes Allergan's worldwide developmental and commercialization rights to EDIT-101. Under the Termination Agreements, Allergan granted the Company a non-exclusive license to certain know-how that is necessary to develop, manufacture and commercialize EDIT-101 and will transfer to the Company certain materials produced under the Collaboration Agreement. The Company will use commercially reasonable efforts to develop and commercialize products directed at four collaboration targets, one of which is LCA10.

In connection with the Termination Agreements, the Company agreed to make a $20.0 million payment to Allergan, $17.5 million of which was paid as of September 30, 2020. In addition, the Company will make certain payments on achievements of clinical and regulatory milestones up to $20.0 million for each target program and aggregated sales milestones for all products covered by the Termination Agreement up to $90.0 million. Allergan is also entitled to royalties in a low-single digit percentage, subject to reduction under specified circumstances, on net sales of specified products. The Company's obligation to pay royalties will expire on a country-by-country and product-by-product basis upon the later of the expiration of regulatory-based exclusivity with respect to such product in such country and the tenth anniversary of the first commercial sale of such product. Lastly, the Company is obligated to pay for a portion of the transition services.

Accounting Assessment

The Company evaluated the Termination Agreements in accordance with the provisions of Accounting Standards Codification ("ASC") 606 and concluded that they resulted in a modification followed by a termination of the Initial Agreements. Upon execution of the Termination Agreements, the Company is no longer obligated to transfer control of any goods or services to Allergan, and therefore there are no remaining performance obligations. As part of this assessment, the Company considered that Allergan relinquished its right to the remaining exclusive license options under the Collaboration Agreement and the Company reacquired the development and commercialization rights to EDIT-101. Allergan no longer has any involvement in the development activities of the collaboration targets. Since there are no remaining performance obligations, the Company accounted for the modification as part of the existing contract with a cumulative catch-up adjustment. The Company applied the vendor consideration to a customer guidance pursuant to ASC 606 in accounting for the $20 million payment due to Allergan and concluded that the worldwide rights to EDIT-101 represent a distinct good or service. The Company therefore recorded the fair value of the rights to EDIT-101 of $5 million as in-process Research and Development expense in the quarter ended September 30, 2020 as the rights had no alternative future use. The remainder of the $20 million was recorded as a reduction to the contract liability that was recognized as revenue upon termination. The contingent payments associated with the collaboration targets not previously licensed by Allergan under the Collaboration Agreement did not impact the amount of deferred revenue recognized upon termination because it is not probable that a significant reversal of revenue will occur. The contingent milestone and royalty payments associated with EDIT-101 qualify for scope exceptions from derivative accounting, and therefore there is no accounting for the contingent payments upon termination.

On the termination date, the Company recognized $62.1 million of previously deferred revenue related to the Collaboration Agreement. This amount consisted of $77.1 million of revenues that were previously deferred related to the collaboration agreement, partially offset by $15.0 million of the fee paid to Allergan that was determined to exceed the fair value of the re-acquired rights to EDIT-101.

During the three and nine months ended September 30, 2020, the Company recognized revenue of $63.2 million and $70.6 million, respectively, related to the Allergan arrangement, including the termination. During the three and nine months ended September 30, 2019, the Company recognized revenue of $3.4 million and $7.7 million, respectively. At September 30, 2020 there was no remaining revenue deferred related to Allergan.

Collaboration Revenue

As of September 30, 2020, the Company's contract liabilities were primarily related to the Company's collaboration with Juno Therapeutics. The following table presents changes in the Company's accounts receivable and contract liabilities for the nine months ended September 30, 2020 (in thousands):

For the nine months ended September 30, 2020	**Balance at December 31, 2019**	**Additions**	**Deductions**	**Balance at September 30, 2020**
Accounts receivable	$ 418	$ 946	$ (309)	$ 1,055
Contract liabilities:				
Deferred revenue	$ 186,721	$ 508	$ (86,534)	$ 100,695

During the three and nine months ended September 30, 2020, the Company recognized the following collaboration revenue (in thousands):

	Three Months Ended	**Nine Months Ended**
Revenue recognized in the period from:	**September 30, 2020**	
Amounts included in deferred revenue at the beginning of the period	$ 78,651	$ 86,534
Performance obligations satisfied in previous periods	$ —	$ 60

9. Stock-based Compensation

Total compensation cost recognized for all stock-based compensation awards in the condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2020	**2019**	**2020**	**2019**
Research and development	$ 2,938	$ 3,619	$ 8,668	$ 10,854
General and administrative	2,908	2,940	8,815	10,053
Total stock-based compensation expense	$ 5,846	$ 6,559	$ 17,483	$ 20,907

Restricted Stock and Restricted Stock Unit Awards

The following is a summary of restricted stock and restricted stock unit awards activity for the nine months ended September 30, 2020:

	Shares	**Weighted Average Grant Date Fair Value Per Share**
Unvested restricted stock and restricted stock unit awards as of December 31, 2019	581,408	$ 24.03
Issued	318,714	$ 28.44
Vested	(279,326)	$ 23.05
Forfeited	(110,918)	$ 24.16
Unvested restricted stock and restricted stock unit awards as of September, 30 2020	509,878	$ 27.38

As of September 30, 2020, total unrecognized compensation expense related to unvested restricted stock and

restricted stock unit awards was $11.9 million, which the Company expects to recognize over a remaining weighted-average period of 2.8 years.

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2020:

	Shares	Weighted Average Exercise Price	Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2019	4,358,291	$ 25.40	7.4	$ 26,060
Granted	1,423,115	$ 28.54		
Exercised	(637,332)	$ 17.00		
Cancelled	(1,103,283)	$ 30.96		
Outstanding at September 30, 2020	4,040,791	$ 26.31	7.9	$ 12,549
Exercisable at September 30, 2020	1,545,508	$ 24.04	7.0	$ 8,973

As of September 30, 2020, total unrecognized compensation expense related to stock options was $39.1 million, which the Company expects to recognize over a remaining weighted-average period of 2.7 years.

10. Net Income (Loss) per Share

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury stock and if converted methods. Contingently issuable shares are included in the calculation of basic income (loss) per share as of the beginning of the period in which all the necessary conditions have been satisfied. Contingently issuable shares are included in diluted income (loss) per share based on the number of shares, if any, that would be issuable under the terms of the arrangement if the end of the reporting period was the end of the contingency period, if the results are dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net income (loss)	$ 7,819	$ (32,941)	$ (53,477)	$ (95,976)
Weighted average common shares outstanding, basic	62,144,118	49,820,455	57,377,581	49,246,684
Dilutive effect of outstanding stock options	414,640	—	—	—
Dilutive effect of unvested restricted stock and restricted stock unit awards	138,415	—	—	—
Weighted average common shares outstanding, diluted	62,697,173	49,820,455	57,377,581	49,246,684
Net income (loss) per share, basic	$ 0.13	$ (0.66)	$ (0.93)	$ (1.95)
Net income (loss) per share, diluted	$ 0.12	$ (0.66)	$ (0.93)	$ (1.95)

The following common stock equivalents were excluded from the calculation of diluted net income (loss) per share allocable to common stockholders because their inclusion would have been anti-dilutive:

	Three Months Ended September 30,		Nine months Ended September 30,	
	2020	2019	2020	2019
Unvested restricted stock and restricted stock unit awards	371,463	586,892	509,878	586,892
Outstanding stock options	3,626,151	5,139,652	4,040,791	5,141,255
Total	3,997,614	5,726,544	4,550,669	5,728,147

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

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission ("SEC") on February 26, 2020 (the "Annual Report").

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. All statements addressing our future operating performance and clinical development and regulatory timelines that we expect or anticipate will occur in the future, are forward-looking statements. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the section entitled "Risk Factors" in Part II, Item 1A that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Overview

We are a leading, clinical stage genome editing company dedicated to developing potentially transformative genomic medicines to treat a broad range of serious diseases. We have developed a proprietary genome editing platform based on CRISPR technology and we continue to expand its capabilities. Our product development strategy is to target diseases of high unmet need where we aim to make differentiated, transformational medicines using our gene editing platform. We are advancing both *in vivo* CRISPR medicines, in which the medicine is injected or infused into the patient to edit the cells inside their body, and engineered cell medicines, in which cells are edited with our technology and then administered to the patient. While our discovery efforts have ranged across several diseases and therapeutic areas, the two areas where our programs are more mature are ocular diseases and engineered cell medicines to treat hemoglobinopathies and cancer.

In ocular diseases, our most advanced program is designed to address a specific genetic form of retinal degeneration called Leber congenital amaurosis 10 ("LCA10"), a disease for which we are not aware of any available therapies and only one other potential treatment in clinical trials in the United States and Europe. In mid-2019, we initiated a Phase 1/2 clinical trial for EDIT-101, an experimental medicine to treat LCA10. The first patient was dosed in the first quarter of 2020 and we plan to enroll approximately 18 patients in the United States and Europe in up to five cohorts. We have completed dosing of the adult low-dose cohort. This trial remains active and open for enrollment. We continue to enroll patients, but enrollment has been slowed due to the ongoing impact of the coronavirus disease of 2019 ("COVID-19") pandemic. For our engineered cell medicines, our lead program is EDIT-301, an experimental medicine to treat sickle cell disease and beta-thalassemia. We have initiated IND-enabling studies for EDIT-301 and aim to submit to the U.S. Food and Drug Administration an investigational new drug application ("IND") for EDIT-301 for the treatment of sickle cell disease by the end of 2020. In addition, EDIT-201 is our experimental allogeneic healthy-donor NK cell medicine for the treatment of solid tumors.

In May 2015, we entered into a collaboration with Juno Therapeutics, Inc., a wholly-owned subsidiary of Bristol-Myers Squibb Company ("Juno Therapeutics"), a leader in the emerging field of immuno-oncology, to develop novel engineered alpha-beta T cell therapies for cancer and autoimmune diseases, which was amended and restated in each of May 2018 and November 2019, at which time we also entered into a related license agreement with Juno Therapeutics, which we collectively refer to as our collaboration with them.

In March 2017, we entered into a strategic alliance and option agreement with Allergan Pharmaceuticals International Limited (which is referred to together with its affiliates as "Allergan"), a leading global pharmaceutical company, to discover, develop, and commercialize new gene editing medicines for a range of ocular disorders. In July 2018, Allergan exercised its option to develop and commercialize EDIT-101 and we subsequently entered into a co-development and commercialization agreement with Allergan under which we will co-develop and equally split profits and losses for EDIT-101 in the United States. Allergan was acquired by AbbVie, Inc. in May 2020. On August 5, 2020, we entered into a termination agreement with Allergan pursuant to which, among other things, we and Allergan terminated the strategic alliance and option agreement and the co-development and commercialization agreement.

As a result of the termination of our collaboration with Allergan, we regained full global rights to research, develop, manufacture, and commercialize our ocular product candidates, including EDIT-101 for the treatment of LCA10. Under the termination agreement, Allergan granted us a non-exclusive, royalty-bearing right and license, including the right to grant sublicenses (through multiple tiers), to certain Allergan know-how that is necessary to develop, manufacture and commercialize EDIT-101. In addition, we are obligated to use commercially reasonable efforts to develop and commercialize a product directed to each of four collaboration targets, one of which is LCA10. Under the termination agreement, we agreed to make a one-time aggregate payment of $20.0 million to Allergan, of which $17.5 million had been paid as of September 30, 2020. In addition, we will make certain payments on achievements of clinical and regulatory milestones up to $20.0 million for each target program and aggregated sales milestones for all products covered by the termination agreement up to $90.0 million. We are also obligated to pay royalties in a low-single digit percentage, subject to reduction under specified circumstances, on net sales of specified products. Our obligation to pay royalties will expire on a country-by-country and product-by-product basis upon the later of the expiration of regulatory-based exclusivity with respect to such product in such country and the tenth anniversary of the first commercial sale of such product. We and Allergan also entered into a transition services agreement to facilitate the transfer of the LCA10 program from Allergan to us. As a result of the termination of the agreements with Allergan, we now have full responsibility for the Phase 1/2 clinical trial for EDIT-101 and expect that our research and development expenses will increase significantly for the foreseeable future as our development programs progress.

Since our inception in September 2013, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, assembling our core capabilities in genome editing, seeking to identify potential product candidates, and undertaking preclinical and clinical studies. Except for EDIT-101, all of our research programs are still in the preclinical or research stage of development and the risk of failure of all of our research programs is high. We have not generated any revenue from product sales. We have primarily financed our operations through various equity financings and payments received under our research collaboration with Juno Therapeutics and our strategic alliance with Allergan.

Since inception, we have incurred significant operating losses. Our net losses were $53.5 million and $96.0 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $602.7 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and from year to year. We anticipate that our expenses will increase substantially as we continue our current research programs and our preclinical development activities, including those related to EDIT-301 and EDIT-201; progress the clinical development of EDIT-101; seek to identify additional research programs and additional product candidates; initiate preclinical testing and clinical trials for other product candidates we identify and develop; maintain, expand, and protect our intellectual property portfolio, including reimbursing our licensors for such expenses related to the intellectual property that we in-license from such licensors; further develop our genome editing platform; hire additional clinical, quality control, and scientific personnel; and incur additional costs associated with operating as a public company. We do not expect to be profitable for the year ending December 31, 2020 or the foreseeable future.

Although we did not experience any significant impact on our financial condition, results of operations or liquidity due to the ongoing COVID-19 pandemic during the nine months ended September 30, 2020, we have recently experienced slowed enrollment in the EDIT-101 clinical trial as a result of the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic, particularly in light of its current resurgence, is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our ability to continue to raise additional capital, the EDIT-101 clinical trial, ongoing preclinical activities, including those related to EDIT-301 and EDIT-201, or the global economy as a whole. In March, we implemented a work from home policy, and restricted on-site activities at our facilities in Massachusetts and Colorado to certain manufacturing, laboratory and related support activities in light of the COVID-19 pandemic. Under our return to onsite work plans, we have resumed manufacturing, laboratory and related support activities at our facilities in Massachusetts and Colorado using shifts and other capacity-limiting measures to comply with social distancing guidelines. As such, it is uncertain as to the full magnitude that the pandemic will have directly or indirectly on our financial condition, liquidity and future results of operations.

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales and we do not expect to generate any revenue from product sales for the foreseeable future. In connection with our collaboration with Juno Therapeutics, we have received an aggregate of $120.0 million in payments, which have primarily consisted of the initial upfront and amendment payments, development milestone payments and research funding support. We no longer receive research funding support. As of September 30, 2020, we recorded $96.3 million of deferred revenue, of which $79.3 million is classified as long-term on our condensed consolidated balance sheet. There was no revenue recognized under the collaboration with Juno Therapeutics during the nine months ended September 30, 2020. Under this collaboration, we will recognize revenue upon delivery of option packages to Juno Therapeutics. We expect that our revenue will fluctuate from quarter-to-quarter and year-to-year as a result of the timing of when we deliver such option packages.

In connection with our strategic alliance with Allergan, we received an aggregate of $130.0 million in payments, which consisted of the initial upfront payment, an option exercise payment and a milestone payment. Prior to the termination of our agreements with Allergan, certain of these payments were deferred and were being recognized over the remaining contract term using the proportional performance method. During the third quarter of 2020, as a result of the termination of our agreements with Allergan, we recognized $63.2 million of previously deferred revenue related to Allergan.

For additional information about our revenue recognition policy related to the Juno Therapeutics collaboration or the Allergan strategic alliance, see "—Critical Accounting Policies and Estimates—Revenue Recognition" included in our Annual Report.

For the foreseeable future we expect substantially all of our revenue will be generated from our collaboration with Juno Therapeutics, and any other collaborations or agreements we may enter into.

Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, which include:

- drug discovery efforts and preclinical and clinical studies under our research programs;
- employee-related expenses including salaries, benefits, and stock-based compensation expense;
- costs of funding research performed by third parties that conduct research and development and preclinical

and clinical activities on our behalf;

- costs of purchasing lab supplies and non-capital equipment used in our preclinical activities and in manufacturing preclinical study materials;
- consultant fees;
- facility costs including rent, depreciation, and maintenance expenses; and
- fees for acquiring and maintaining licenses under our third-party licensing agreements, including any sublicensing or success payments made to our licensors.

Research and development costs are expensed as incurred. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of any product candidates we may identify and develop. This is due to the numerous risks and uncertainties associated with developing such product candidates, including the uncertainty of:

- successful completion of preclinical studies, IND-enabling studies and natural history studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical, commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of a product, if and when approved, whether alone or in collaboration with others;
- acceptance of a product, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these variables with respect to the development of any product candidates we develop would significantly change the costs, timing, and viability associated with the development of that product candidate. As a result of the termination of our profit-sharing arrangement with Allergan in the United States for EDIT-101, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States.

We do not track research and development costs on a program-by-program basis except for reimbursable amounts that relate to third-party arrangements.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, including as we continue to progress the clinical development of EDIT-101 as well as supporting preclinical studies for our other research programs, including EDIT-301.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in executive, finance, investor relations, business development, legal, corporate affairs, information technology, facilities and human resource functions. Other significant costs include corporate facility costs not otherwise included in research and development expenses, legal fees related to intellectual property and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities and potential commercialization of any product candidates we identify and develop. These increases will include increased costs related to the hiring of additional personnel and fees to outside consultants. We also anticipate increased expenses related to reimbursement of third-party patent-related expenses and expenses associated with operating as a public company, including costs for audit, legal, regulatory, and tax-related services, director and officer insurance premiums, and investor relations costs. With respect to reimbursement of third-party intellectual property-related expenses specifically, given the ongoing nature of the opposition, interference and re-examination proceedings involving the patents licensed to us under our license agreements with The Broad Institute, Inc. (“Broad”) and the President and Fellows of Harvard College (“Harvard”), we anticipate general and administrative expenses will continue to be significant.

Other (Expense) Income, Net

For the nine months ended September 30, 2020, other (expense) income, net consisted primarily of changes in the fair value of equity securities, interest income and accretion of discounts associated with other marketable securities.

For the nine months ended September 30, 2019, other (expense) income, net consisted primarily of interest income and accretion of discounts associated with marketable securities, partially offset by loss on disposal of property and equipment.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of our condensed consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses, and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the condensed consolidated financial statements prospectively from the date of change in estimates.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Results of Operations

Comparison of the Three Months ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Three Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Collaboration and other research and development revenues	$ 62,841	$ 3,848	$ 58,993	n/m %
Operating expenses:				
Research and development	33,916	22,702	11,214	49 %
General and administrative	19,936	15,734	4,202	27 %
Total operating expenses	53,852	38,436	15,416	40 %
Other (expense) income, net:				
Other expense, net	(1,396)	(33)	(1,363)	n/m %
Interest income, net	226	1,680	(1,454)	(87) %
Total other (expense) income, net	(1,170)	1,647	(2,817)	n/m %
Net income (loss)	$ 7,819	$ (32,941)	$ 40,760	n/m %

For our results of operations, we have included the respective percentage of changes, unless greater than 100% or less than (100)%, in which case we have denoted such changes as not meaningful (n/m).

Collaboration and other research and development revenues

Collaboration and other research and development revenues increased by $59.0 million, to $62.8 million for the three months ended September 30, 2020 from $3.8 million for three months ended September 30, 2019. This increase was primarily attributable to the recognition of $59.9 million of previously deferred revenue as a result of the termination of our strategic alliance with Allergan.

Research and development expenses

Research and development expenses increased by $11.2 million, to $33.9 million for the three months ended September 30, 2020 from $22.7 million for the three months ended September 30, 2019. The following table summarizes our research and development expenses for the three months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Three Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Process and platform development expenses	$ 18,204	$ 9,334	$ 8,870	95 %
Employee related expenses	8,072	6,357	1,715	27 %
Facility expenses	3,617	2,468	1,149	47 %
Stock-based compensation expenses	2,938	3,619	(681)	(19) %
Other expenses	893	721	172	24 %
Sublicense and license fees	192	203	(11)	— %
Total research and development expenses	$ 33,916	$ 22,702	$ 11,214	49 %

The increase in research and development expenses for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was primarily attributable to:

- approximately $8.9 million in increased process and platform development expenses related primarily to the clinical and manufacturing development of EDIT-101 and our other programs, including a one-time in-process research and development expense of $5.0 million for re-acquiring the rights to EDIT-101 from Allergan;
- approximately $1.7 million in increased employee related expenses primarily due to an increase in the size of our workforce including the expansion of our research and development organization;
- approximately $1.1 million in increased facility related expenses; and
- approximately $0.2 million in increased other expenses.

These increases were partially offset by approximately $0.7 million in decreased stock-based compensation expenses resulting from forfeitures.

As a result of the termination of our agreements with Allergan, we expect that our research and development costs will increase as we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States. In addition, we anticipate that we will increase headcount in our clinical and development organization as a result of the transfer from Allergan to us of the Phase 1/2 clinical trial of EDIT-101 for the treatment of LCA10 as part of the termination of the arrangement with Allergan.

General and administrative expenses

General and administrative expenses increased by $4.2 million, to $19.9 million for the three months ended September 30, 2020 from $15.7 million for the three months ended September 30, 2019.The following table summarizes our general and administrative expenses for the three months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Three Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Professional service expenses	$ 6,314	$ 3,980	$ 2,334	59 %
Intellectual property and patent related fees	4,446	4,227	219	5 %
Employee related expenses	4,164	3,311	853	26 %
Stock-based compensation expenses	2,908	2,940	(32)	(1)%
Facility and other expenses	2,104	1,276	828	65 %
Total general and administrative expenses	$ 19,936	$ 15,734	$ 4,202	27 %

The increase in general and administrative expenses for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was primarily attributable to:

- approximately $2.3 million in increased professional service expenses in connection with the termination of the Allergan agreement;
- approximately $0.9 million in increased employee related expenses primarily due to an increase in the size of our workforce and the timing of hiring key executives;
- approximately $0.8 million in increased facility and other expenses resulting from additional office space leased in 2020; and

- approximately $0.2 million in increased intellectual property and patent related fees.

Other (expense) income, net

For the three months ended September 30, 2020, other (expense) income, net was an expense of $1.2 million, which was primarily attributable to the unrealized losses related to corporate equity securities, partially offset by interest income.

For the three months ended September 30, 2019, other (expense) income, net was income of $1.6 million, which was primarily attributable to interest income and accretion of discounts associated with marketable securities.

Comparison of the Nine Months ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Nine Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Collaboration and other research and development revenues	$ 79,313	$ 8,247	$ 71,066	n/m %
Operating expenses:				
Research and development	96,492	62,109	34,383	55 %
General and administrative	51,789	47,638	4,151	9 %
Total operating expenses	148,281	109,747	38,534	35 %
Other income, net				
Other income (expense), net	13,114	(144)	13,258	n/m %
Interest income, net	2,377	5,668	(3,291)	(58)%
Total other income, net	15,491	5,524	9,967	n/m %
Net loss	$ (53,477)	$ (95,976)	$ 42,499	(44)%

For our results of operations, we have included the respective percentage of changes, unless greater than 100% or less than (100)%, in which case we have denoted such changes as not meaningful (n/m).

Collaboration and other research and development revenues

Collaboration and other research and development revenues increased by $71.1 million to $79.3 million for the nine months ended September 30, 2020 from $8.2 million for the nine months ended September 30, 2019. This increase was primarily attributable to the recognition of $63.0 million of previously deferred revenue as a result of the termination of our strategic alliance with Allergan, as well as an increase of $7.7 million in revenue recognized pursuant to an out-license agreement we entered into during the second quarter of 2020, and a $0.4 million increase in revenue recognized pursuant to other license and collaboration arrangements during the nine months ended September 30, 2020.

Research and development expenses

Research and development expenses increased by $34.4 million, to $96.5 million for the nine months ended September 30, 2020 from $62.1 million for the nine months ended September 30, 2019. The following table summarizes our research and development expenses for the nine months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Nine Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Process and platform development expenses	$ 46,162	$ 24,351	$ 21,811	90 %
Employee related expenses	24,589	17,054	7,535	44 %
Facility expenses	9,909	6,338	3,571	56 %
Stock-based compensation expenses	8,668	10,854	(2,186)	(20)%
Sublicense and license fees	4,132	1,036	3,096	n/m %
Other expenses	3,032	2,476	556	n/m %
Total research and development expenses	$ 96,492	$ 62,109	$ 34,383	55 %

The increase in research and development expenses for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily attributable to:

- approximately $21.8 million in increased process and platform development expenses related primarily to the clinical and manufacturing development of EDIT-101 and our other programs, including a one-time in-process research and development expense of $5.0 million for re-acquiring the rights to EDIT-101 from Allergan and expenses incurred under the profit-sharing arrangement with Allergan related to EDIT-101 prior to the termination of the agreement and expenses incurred related to an in-license arrangement entered into during the first quarter of 2020;

- approximately $7.5 million in increased employee related expenses primarily due to an increase in the size of our workforce including the expansion of our development organization;

- approximately $3.6 million in increased facility expenses primarily due additional lab and manufacturing space leased in 2020;

- approximately $3.1 million in increased sublicense and license fees primarily related to sublicense fees that were owed to our licensors in connection with an out-license agreement that we entered into during the second quarter of 2020 and additional license fees that we incurred during the quarter; and

- approximately $0.6 million in increased other expenses primarily due to increase software license fees.

These increases were partially offset by approximately $2.2 million in decreased stock-based compensation expenses resulting primarily from forfeitures.

As a result of the termination of our agreements with Allergan, we expect that our research and development costs will increase as we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States. In addition, we anticipate that we will increase headcount in our clinical and development organization as a result of the transfer from Allergan to us of the Phase 1/2 clinical trial of EDIT 101 for the treatment of LCA10 as part of the termination of the agreement with Allergan.

General and administrative expenses

General and administrative expenses increased by $4.2 million, to $51.8 million for the nine months ended September 30, 2020 from $47.6 million for the nine months ended September 30, 2019. The following table summarizes our general and administrative expenses for the nine months ended September 30, 2020 and 2019, together with the changes in those items in dollars (in thousands) and the respective percentages of change:

	Nine Months Ended September 30,			
	2020	2019	Dollar Change	Percentage Change
Intellectual property and patent related fees	$ 13,457	$ 13,570	$ (113)	(1)%
Employee related expenses	12,616	9,571	3,045	32 %
Professional service expenses	10,803	10,809	(6)	(0)%
Stock-based compensation expenses	8,815	10,053	(1,238)	(12)%
Facility and other expenses	6,098	3,635	2,463	68 %
Total general and administrative expenses	$ 51,789	$ 47,638	$ 4,151	9 %

The increase in general and administrative expenses for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily attributable to:

- approximately $3.0 million in increased employee related expenses primarily due to an increase in the size of our workforce and the timing of hiring key executives; and
- approximately $2.5 million in increased facility and other expenses resulting from additional office space leased in 2020.

These increases were partially offset by approximately $1.2 million in decreased stock-based compensation expenses resulting from a modification that occurred in 2019 with respect to which there was no similar activity for in 2020 and approximately $0.1 million in decreased intellectual property and patent related expenses.

Other (expense) income, net

For the nine months ended September 30, 2020, other (expense) income, net was income of $15.5 million, which was primarily attributable to the unrealized gains related to corporate equity securities, interest income and accretion of discounts associated with marketable securities.

For the nine months ended September 30, 2019, other (expense) income, net was income of $5.5 million, which was primarily attributable to interest income and accretion of discounts associated with marketable securities, partially offset by a loss on disposal of property and equipment.

Liquidity and Capital Resources

Sources of Liquidity

In May 2020, we entered into a sales agreement with Cowen and Company, LLC ("Cowen") under which we are able from time to time to issue and sell shares of our common stock through Cowen for aggregate gross sales proceeds of up to $150.0 million (the "ATM Facility"). We have not sold any shares of our common stock under this ATM Facility as of the date of this Quarterly Report on Form 10-Q. In June 2020, we completed a public offering whereby we sold 6,900,000 shares of our common stock, inclusive of 900,000 shares of common stock sold by us pursuant to the full exercise of an option granted to the underwriters in connection with the offering and received net process of approximately $203.7 million. As of September 30, 2020, we have raised an aggregate of $648.7 million in net proceeds through the sale of shares of our common stock in public offerings and at-the-market offerings. We also have funded our business from payments received under our research collaboration with Juno Therapeutics and our strategic alliance with Allergan, which was terminated in August 2020. As of September 30, 2020, we had cash, cash equivalents and marketable securities of $541.3 million.

In addition to our existing cash, cash equivalents and marketable securities we are eligible to earn milestone and other payments under our collaboration agreement with Juno Therapeutics. Our ability to earn the milestone payments and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and, as such, are uncertain at this time. As of September 30, 2020, our right to contingent payments under our collaboration agreement with Juno Therapeutics is our only significant committed potential external source of funds.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Net cash (used in) provided by:		
Operating activities	$ (139,742)	$ (81,693)
Investing activities	(31,628)	4,434
Financing activities	215,022	47,255
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 43,652	$ (30,004)

Net Cash Used in Operating Activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was approximately $139.7 million for the nine months ended September 30, 2020, which primarily consisted of operating expenses that relate to our on-going preclinical and clinical activities, patent costs and license fees, and increased costs as a result of staffing needs due to our expanding operations. These expenses were partially offset by cash inflows from license fees received in the period.

Net cash used in operating activities was approximately $81.7 million for the nine months ended September 30, 2019, which primarily consisted of operating expenses that related to our strategic alliance with Allergan which decreased deferred revenue, partially offset by an upfront payment received related to an out-license arrangement. This amount was offset by operating expenses that related to our on-going preclinical and clinical activities, patent costs and license fees, costs related to obtaining additional research facilities and increased costs as a result of staffing needs due to our expanding operations.

Net Cash Used in Investing Activities

Net cash used in investing activities was approximately $31.6 million for the nine months ended September 30, 2020, primarily related to costs used to acquire marketable securities of $300.4 million and costs to acquire property and equipment of $5.8 million, partially offset by proceeds from maturities of marketable securities of $274.5 million.

Net cash provided by investing activities was approximately $4.4 million for the nine months ended September 30, 2019, primarily related to higher proceeds from maturities of marketable securities than purchases of marketable securities that were partially offset by $4.5 million in equipment purchases.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately $215.0 million for the nine months ended September 30, 2020, and consisted of $203.8 million in net proceeds received from offering of common stock, of which $0.2 million of expenses related to the offering were unpaid at quarter-end, and $10.8 million in proceeds received from exercises of options for our common stock.

Net cash provided by financing activities was approximately $47.2 million for the nine months ended September 30, 2019, and consisted of $41.2 million in proceeds received from at-the-market offerings of our common stock, $5.8 million in proceeds from exercises of options for our common stock and $0.3 million from the issuance of our common stock under our equity plans.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we progress the clinical development of EDIT-101; further advance our current research programs and our preclinical development activities, including those related to EDIT-301 and EDIT-201; seek to identify product candidates and additional research programs; initiate preclinical testing and clinical trials for other product candidates we identify and develop; maintain, expand, and protect our intellectual property portfolio, including reimbursing our licensors for expenses related to the intellectual property that we in-license from such licensors; hire additional clinical, quality control, and scientific personnel; and incur costs associated with operating as a public company. In addition, if we obtain marketing approval for any product candidate that we identify and develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, and distribution are not the responsibility of a collaborator. We do not expect to generate significant recurring revenue unless and until we obtain regulatory approval for and commercialize a product candidate. Furthermore, since 2016 we have incurred, and in future years we expect to continue to incur, significant costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents and marketable securities at September 30, 2020 and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and clinical or natural history study trials for the product candidates we develop;
- the costs of progressing the clinical development of EDIT-101 to treat LCA10;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;

- the costs, timing, and outcome of regulatory review of the product candidates we develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any product candidates for which we receive regulatory approval;
- the success of our collaboration with Juno Therapeutics;
- whether Juno Therapeutics exercises any of its options to extend the research program term and/or to certain of the research programs under our collaboration;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs of reimbursing our licensors for the prosecution and maintenance of the patent rights in-licensed by us; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive, and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, any product candidate that we identify and develop, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of genomic medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. Further, our ability to continue to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

During the nine months ended September 30, 2020, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report.

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 applicable SEC rules.

Effects of Inflation

Inflation would generally affect our business by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2020 or 2019.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2020, we had cash and cash equivalents of $279.6 million, primarily held in money market mutual funds consisting of U.S. government-backed securities, and marketable securities of $215.7 million, primarily consisting of U.S. government-backed securities, corporate equity securities and corporate debt 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, particularly because our investments, including cash equivalents, are in the form, or may be in the form of, money market funds or marketable securities and are or may be invested in U.S. Treasury and U.S. government agency obligations. Due to the short-term maturities and low risk profiles of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our investments.

While we contract with certain vendors and institutions internationally, substantially all of our total liabilities as of September 30, 2020 were denominated in the United States dollar and we believe that we do not have any material exposure to foreign currency exchange rate risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. There can be no assurance that any proceedings that result from these third-party actions will be resolved in our favor. In addition, if they are not resolved in our favor, there can be no assurance that the result will not have a material adverse effect on our business, financial condition, results of operations, or prospects. Certain of our intellectual property rights, including ones licensed to us under our licensing agreements, are subject to, and from time to time may be subject to, priority and validity disputes. For additional information regarding these matters, see "Item 1A. Risk Factors—Risks Related to Our Intellectual Property." Regardless of outcome, litigation or other legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors.

Our business is subject to numerous risks. The following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the Securities and Exchange Commission (the "SEC"), press releases, communications with investors, and oral statements. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net losses were $133.7 million, $110.0 million, and $120.3 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of September 30, 2020, we had an accumulated deficit of $602.7 million. We have financed our operations primarily through public offerings of our common stock, private placements of our preferred stock, our collaboration with Juno Therapeutics, Inc., a wholly-owned subsidiary of Bristol-Myers Squibb Company ("Juno Therapeutics"), and payments under our strategic alliance with Allergan Pharmaceuticals International Limited (which was acquired by AbbVie Inc. in May 2020 and is referred to together with its affiliates as "Allergan"), which was terminated in August 2020. We have devoted substantially all of our efforts to research and development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- progress the clinical development of EDIT-101 to treat Leber congenital amaurosis ("LCA") 10 ("LCA10");
- continue our current research programs and our preclinical development of product candidates from our current research programs, including EDIT-301, our experimental medicine to treat sickle cell disease and beta-thalassemia;
- seek to identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop;
- maintain, expand, and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;

- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval;
- further develop our genome editing platform;
- hire additional clinical, quality control, and scientific personnel;
- add operational, financial, and management information systems and personnel, including personnel to support our product development;
- acquire or in-license other medicines and technologies;
- validate a commercial-scale current Good Manufacturing Practices ("cGMP") manufacturing facility; and
- continue to operate as a public company.

We are in the early stages of the clinical development of EDIT-101 and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. As a result of the termination of our agreements with Allergan in August 2020, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101. To become and remain profitable, we must develop and eventually commercialize a medicine or medicines with significant market potential. This will require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, and selling those medicines for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. Other than EDIT-101, we are currently only in the preclinical testing stages for our most advanced research programs. 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 our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investments in us.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our research and product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate clinical trials of, and seek marketing approval for, product candidates. In addition, if we obtain marketing approval for any product candidates we develop, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our research and product development programs or future commercialization efforts.

We expect that our existing cash, cash equivalents, and marketable securities at September 30, 2020 and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements into 2023. Our future capital requirements will depend on many factors, including:

- the costs of progressing the clinical development of EDIT-101 to treat LCA10;
- the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and clinical or natural history study trials for the product candidates we develop;

- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;
- the costs, timing, and outcome of regulatory review of the product candidates we develop;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any product candidates for which we receive regulatory approval;
- the success of our collaboration with Juno Therapeutics;
- whether Juno Therapeutics exercises any of its options to extend the research program term and/or to certain of the research programs under our collaboration;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other medicines and technologies;
- the costs of reimbursing our licensors for the prosecution and maintenance of the patent rights in-licensed by us; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, even if we successfully identify and develop product candidates and those are approved, we may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. We do not have any significant committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our short operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

We are an early-stage company. We were founded and commenced operations in the second half of 2013. Our

operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, undertaking preclinical studies and preparing to undertake clinical trials. Except for EDIT-101 to treat LCA10, all of our research programs are still in the preclinical or research stage of development, and the risk of failure of all of our research programs is high. We have not yet demonstrated an ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale medicine, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect that our financial condition and operating results will continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, our stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, product candidates we may identify for development. We do not anticipate generating revenues from product sales for the next several years, if ever. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- identify product candidates and complete research and preclinical and clinical development of any product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials;
- launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure;
- qualify for adequate coverage and reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we develop;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of any product candidates we develop as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;

- negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such arrangements;
- maintain, protect, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- avoid and defend against third-party interference or infringement claims; and
- attract, hire, and retain qualified personnel.

Even if one or more of the product candidates we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the "FDA"), the European Medicines Agency (the "EMA"), or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Risks Related to Discovery, Development, and Commercialization

We intend to identify and develop product candidates based on a novel genome editing technology, which makes it difficult to predict the time and cost of product candidate development. No therapeutic products that utilize genome editing technology have been approved in the United States or in Europe, and there have only been a limited number of human clinical trials of a genome editing product candidate.

We have concentrated our research and development efforts on our genome editing platform, which uses CRISPR technology. Our future success depends on the successful development of this novel genome editing therapeutic approach. To date, no therapeutic product that utilizes genome editing, including CRISPR technology, has been approved in the United States or Europe and there have been only a limited number of clinical trials involving the use of a therapeutic utilizing genome editing technologies. As we have not yet been able to fully assess safety in humans, there may be long-term effects from treatment with any of our future product candidates that we cannot predict at this time. Any product candidates we develop will act at the level of DNA, and, because animal DNA differs from human DNA, it will be difficult for us to test our future product candidates in animal models for either safety or efficacy. Also, animal models do not exist for some of the diseases we expect to pursue in our programs. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our genome editing platform, or any similar or competitive genome editing platforms, will result in the identification, development, and regulatory approval of any medicines. There can be no assurance that any development problems we experience in the future related to our genome editing platform or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we develop on a timely or profitable basis, if at all.

Because genome editing is novel and the regulatory landscape that will govern any product candidates we develop is uncertain and may change, we cannot predict the time and cost of obtaining regulatory approval, if we receive it at all, for any product candidates we develop.

The regulatory requirements that will govern any novel genome editing product candidates we develop are not entirely clear and may change. Within the broader genomic medicine field, we are aware of a limited number of gene therapy products that have received marketing authorization from the FDA and the EMA. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in

the United States, the FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research ("CBER") to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee ("IBC"), a committee that reviews and oversees the use of biological agents. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and allowed its initiation. The same applies in the European Union. The EMA's Committee for Advanced Therapies ("CAT") is responsible for assessing the quality, safety, and efficacy of advanced-therapy medicinal products. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant European Union guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any CRISPR product candidates we develop, but that remains uncertain at this point.

Adverse developments in clinical trials conducted by others of gene therapy products, cell therapy products, or products developed through the application of a CRISPR or other genome editing technology may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post-approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop.

Adverse public perception of genomic medicines, and genome editing in particular, may negatively impact regulatory approval of, or demand for, our potential products.

Our potential therapeutic products involve editing the human genome. The clinical and commercial success of our potential products will depend in part on public understanding and acceptance of the use of genome editing therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genome editing is unsafe, unethical, or immoral, and, consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

In addition, genome editing technology is subject to public debate and heightened regulatory scrutiny due to ethical concerns relating to the application of genome editing technology to human embryos or the human germline. For example, academic scientists in several countries, including the United States, have reported on their attempts to edit the genome of human embryos as part of basic research and, in November 2018, Dr. Jiankui He, a Chinese biophysics researcher who was an associate professor in the Department of Biology of the Southern University of Science and

Technology in Shenzhen, China, announced he had created the first human genetically edited babies, twin girls and helped create a second gene-edited pregnancy. The announcement was negatively received by the public, in particular by those in the scientific community. In the United States, germline editing for clinical application has been expressly prohibited since enactment of a December 2015 U.S. FDA ban on such activity. Prohibitions are also in place in the United Kingdom, across most of Europe, in China, and many other countries around the world. In the United States, the National Institutes of Health ("NIH") has announced that it would not fund any use of genome editing technologies in human embryos, noting that there are multiple existing legislative and regulatory prohibitions against such work, including the Dickey-Wicker Amendment, which prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. Laws in the United Kingdom prohibit genetically modified embryos from being implanted into women, but embryos can be altered in research labs under license from the Human Fertilisation and Embryology Authority. Basic research on embryos is more tightly controlled in many other European countries.

Moreover, in an annual worldwide threat assessment report delivered to the U.S. Congress in February 2016, the U.S. Director of National Intelligence stated that research into genome editing probably increases the risk of the creation of potentially harmful biological agents or products, including weapons of mass destruction. He noted that the broad distribution, low cost, and accelerated pace of development of genome editing technology could result in the deliberate or unintentional misuse of such technology.

Although we do not use our technologies to edit human embryos or the human germline, such public debate about the use of genome editing technologies in human embryos and heightened regulatory scrutiny could prevent or delay our development of product candidates. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for any products we may develop. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing genome editing technologies, even if not ultimately attributable to product candidates we may identify and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we may identify and develop, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. Use of genome editing technology by a third party or government to develop biological agents or products that threaten the United States' national security could similarly result in such negative impacts to us.

We may not be successful in our efforts to identify, develop, or commercialize potential product candidates.

The success of our business depends primarily upon our ability to identify, develop, and commercialize products based on our genome editing platform. Other than EDIT-101 to treat LCA10, all of our product development programs are still in the preclinical or research stage of development. Our research programs, including those subject to our collaboration with Juno Therapeutics, may fail to identify potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products impractical to manufacture, unmarketable, or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

The genome editing field is relatively new and is evolving rapidly. We are focusing our research and development efforts on CRISPR gene editing technology using Cas9 and Cas12a enzymes, but other genome editing technologies may be discovered that provide significant advantages over CRISPR/Cas9 or CRISPR/Cas12a, which could materially harm our business.

To date, we have focused our efforts on genome editing technologies using CRISPR and the Cas9 and Cas12a

(also known as Cpf1) enzymes. Other companies have previously undertaken research and development of genome editing technologies using zinc finger nucleases, engineered meganucleases, and transcription activator-like effector nucleases, but to date none has obtained marketing approval for a product candidate. There can be no certainty that the CRISPR/Cas9 or CRISPR/Cas12a technology will lead to the development of genomic medicines, that other genome editing technologies will not be considered better or more attractive for the development of medicines or that either Cas9 or Cas12a, the two CRISPR associated proteins that we use, may be useful or successful in developing therapeutics. For example, Cas9 or Cas12a may be determined to be less attractive than other CRISPR enzymes, including CRISPR enzymes that have yet to be discovered. Similarly, a new genome editing technology that has not been discovered yet may be determined to be more attractive than CRISPR. Moreover, if we decide to develop genome technologies other than CRISPR technology using a Cas9 or Cas12a enzyme, we cannot be certain we will be able to obtain rights to such technologies. Any of these factors could reduce or eliminate our commercial opportunity, and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We depend heavily on the success of EDIT-101. Except for EDIT-101, all of our product development programs are at the preclinical or research stage. Preclinical testing and clinical trials of product candidates may not be successful. If we are unable to commercialize any product candidates we develop or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification and development of EDIT-101 to treat LCA10. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of EDIT-101 for the treatment of LCA10 and other product candidates that we may identify in the future. As a result of the termination of our collaboration with Allergan in August 2020, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101, and will need to expand our clinical development organization. Previously, we relied on Allergan to conduct the Phase 1/2 clinical trial of EDIT-101 and we do not have experience conducting Phase 1/2 clinical trials. Although we have entered into a transition services agreement with Allergan to facilitate the transfer of the LCA10 program, including the Phase 1/2 clinical trial, there can be no assurance that the transition of the program will not cause delays in the clinical trial timeline or cost more than we anticipate. The success of product candidates we identify and develop will depend on many factors, including the following:

- sufficiency of our financial and other resources to complete the necessary clinical trials for EDIT-101;
- successful completion of preclinical studies and investigational new drug ("IND")-enabling studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our medicines;
- launching commercial sales of the medicines, if and when approved, whether alone or in collaboration with others;
- acceptance of the medicines, if and when approved, by patients, the medical community, and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile of the medicines following approval;

- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

The foregoing also applies to our collaborators to the extent we have partnered, sold or licensed any of our research programs to them. If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we develop, which would materially harm our business.

Of the large number of biologics and drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a Biologics License Application (a "BLA") to the FDA or a marketing authorization application (an "MAA") to the EMA. Not all BLAs or MAAs that are submitted to a regulatory agency are approved for commercialization. Furthermore, even if we do receive regulatory approval to market any product candidates that we may identify and develop, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research programs, we cannot assure you that we or our collaborators will successfully develop or commercialize EDIT-101, or any of our other research programs. If we or any of our collaborators and future development partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize, any product candidates we may identify and develop, we may not be able to generate sufficient revenue to continue our business.

If serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any product candidates we develop, we may need to abandon or limit our further clinical development of those product candidates.

Other than in connection with the EDIT-101 Phase 1/2 clinical trial, for which we began dosing patients in 2020 and is in the early stages of assessing safety, we have not evaluated any product candidates in human clinical trials, and our proposed delivery modes, combined with CRISPR technology, have a limited history, if any, of being tested clinically. It is impossible to predict when or if any product candidates we develop will ultimately prove safe in humans, including EDIT-101. In the genomic medicine field, there have been several significant adverse events from gene therapy treatments in the past, including reported cases of leukemia and death. There can be no assurance that genome editing technologies will not cause severe or undesirable side effects.

A significant risk in any genome editing product is that the edit will be "off-target" and cause serious adverse events, undesirable side effects, or unexpected characteristics. For example, off-target cuts could lead to disruption of a gene or a genetic regulatory sequence at an unintended site in the DNA, or, in those instances where we also provide a segment of DNA to serve as a repair template, it is possible that following off-target cut events, DNA from such repair template could be integrated into the genome at an unintended site, potentially disrupting another important gene or genomic element. We cannot be certain that off-target editing will not occur in any of our clinical studies. There is also the potential risk of delayed adverse events following exposure to genome editing therapy due to the potential for persistent biological activity of the genetic material or other components of products used to carry the genetic material.

If any product candidates we develop are associated with serious adverse events, or undesirable side effects, or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects. Many product candidates that initially showed promise in early stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further clinical development of the product candidates.

If any of the product candidates we develop or the delivery modes we rely on cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

Our product candidates that we are testing or may test in clinical trials, including EDIT-101, or that are

developed may be associated with off-target editing or other serious adverse events, undesirable side effects, or unexpected characteristics. There also is the potential risk of delayed adverse events following exposure to gene editing therapy due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. In addition to serious adverse events or side effects caused by any product candidate we develop and test, the administration process or related procedures also can cause undesirable side effects. If any such events occur, our clinical trials could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any product candidates we are able to develop for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any product candidate we develop, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations, and prospects significantly.

Additionally, if we successfully develop a product candidate and it receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment with such product candidate outweighs the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, if we or others later identify undesirable side effects caused by any of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any product candidates we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have not extensively tested any of our proposed delivery modes and product candidates in clinical trials.

Our proposed delivery modes, combined with our product candidates, have a limited history of being evaluated in human clinical trials. Any of our product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical trials.

There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit, or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

Any such adverse events may cause us to delay, limit, or terminate planned clinical trials, any of which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Because we are developing product candidates for the treatment of diseases in which there is little clinical experience using new technologies, there is increased risk that the FDA, the EMA, or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

During the regulatory review process, we will need to identify success criteria and endpoints such that the FDA, the EMA, or other regulatory authorities will be able to determine the clinical efficacy and safety profile of our product candidates. As we are seeking to identify and develop product candidates to treat diseases in which there is little clinical experience using new technologies, there is heightened risk that the FDA, the EMA, or other regulatory authorities may not consider the clinical trial endpoints that we propose to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. This may be a particularly significant risk for many of the genetically defined diseases for which we plan to develop product candidates because many of these diseases have small patient populations, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Further, even if we do achieve the pre-specified criteria, we may produce results that are unpredictable or inconsistent with the results of the non-primary endpoints or other relevant data. The FDA also weighs the benefits of a product against its risks, and the FDA may view the efficacy results in the context of safety as not being supportive of regulatory approval. Other regulatory authorities in the European Union and other countries, such as the CAT, may make similar comments with respect to these endpoints and data. Any product candidates we develop will be based on a novel technology that makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. No genome editing therapeutic product has been approved in the United States or in Europe.

If clinical trials of any product candidates we may identify and develop fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy in humans of any such product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur 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. 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 product candidates.

We or our collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any product candidates we may identify and develop, including:

- delays related to the transfer of the LCA10 program, including the Phase 1/2 clinical trial for EDIT-101, from Allergan to us;
- delays in reaching a consensus with regulators on trial design;

- regulators, institutional review boards ("IRBs") or independent ethics committees ("IECs") may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching or failing to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective contract research organizations ("CROs") and clinical trial sites;
- clinical trials of any product candidates we develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development or research programs;
- difficulty in designing well-controlled clinical trials due to ethical considerations which may render it inappropriate to conduct a trial with a control arm that can be effectively compared to a treatment arm;
- difficulty in designing clinical trials and selecting endpoints for diseases that have not been well-studied and for which the natural history and course of the disease is poorly understood;
- the number of patients required for clinical trials of any product candidates we develop may be larger than we anticipate; enrollment of suitable participants in these clinical trials, which may be particularly challenging for some of the rare genetically defined diseases we are targeting in our most advanced programs, may be delayed or slower than we anticipate; or patients may drop out of these clinical trials 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;
- regulators, IRBs, or IECs may require that we or our investigators suspend or terminate clinical research or clinical trials of any product candidates we develop for various reasons, including noncompliance with regulatory requirements, a finding of undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks or after an inspection of our clinical trial operations or trial sites;
- the cost of clinical trials of any product candidates we develop may be greater than we anticipate;
- the supply or quality of any product candidates we develop or other materials necessary to conduct clinical trials of any product candidates we develop may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing, and delivery of any product candidates we develop to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical trial sites dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- occurrence of serious adverse events associated with any product candidates we develop that are viewed to outweigh their potential benefits;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

If we or our collaborators are required to conduct additional clinical trials or other testing of any product candidates we develop beyond those that we currently contemplate, if we or our collaborators are unable to successfully complete clinical trials of any product candidates we develop or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we or our collaborators may:

- be delayed in obtaining marketing approval for any such product candidates we develop or not obtain marketing approval 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, including boxed warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

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

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We or our collaborators may not be able to initiate or continue clinical trials for any of our 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 analogous regulatory authorities outside the United States, or as needed to provide appropriate statistical power for a given trial. Enrollment may be challenging for the rare genetically defined diseases we are targeting. In addition, if patients are unwilling to participate in our genome editing trials because of negative publicity from adverse events related to the biotechnology, gene therapy, or genome editing fields, competitive clinical trials for similar patient populations, clinical trials in competing products, or for other reasons, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of any product candidates we develop may be delayed. Moreover, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as any product candidates we develop, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For example, ProQR Therapeutics N.V. has already enrolled LCA10 patients in its clinical trial, which may limit the number of potential patients available to enroll in the ongoing Phase 1/2 clinical trial for EDIT-101.

Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;

- size of the patient population and process for identifying patients;
- design of the trial protocol;
- availability and efficacy of approved medications for the disease under investigation;
- availability of genetic testing for potential patients;
- ability to obtain and maintain patient informed consent;
- risk that enrolled patients will drop out before completion of the trial;
- eligibility and exclusion criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- perceived risks and benefits of genome editing as a therapeutic approach;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment;
- the ongoing coronavirus disease of 2019 ("COVID-19") pandemic; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, EDIT-101 for the treatment of LCA10 has a limited patient pool from which to draw for enrollment in a clinical trial, as the global incidence of LCA10 is estimated to be two to three per 100,000 live births worldwide. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. We have recently experienced slowed enrollment in the EDIT-101 clinical trial resulting from the impact of the COVID-19 pandemic, including international travel restrictions imposed in response to the pandemic. The ultimate impact of the COVID-19 pandemic on enrollment of the EDIT-101 trial, particularly in light of the pandemic's current resurgence, is highly uncertain and we do not yet know the full extent of potential delays or impacts on the EDIT-101 clinical trial.

Our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- different standard-of-care for patients with a particular disease;
- inability to locate qualified local consultants, physicians, and partners; and
- potential burden of complying with a variety of foreign laws, medical standards, and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

Enrollment delays in our clinical trials may result in increased development costs for any of our product

candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. If we or our collaborators have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and our product candidates for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable medicines. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to successfully identify patients who are likely to benefit from therapy with any medicines we develop, or experience significant delays in doing so, we may not realize the full commercial potential of any medicines we may develop.

Our success may depend, in part, on our ability to identify patients who are likely to benefit from therapy with any of our medicines, which may require those potential patients to have their DNA analyzed for the presence or absence of a particular sequence. For example, although LCA can be diagnosed based on a patient's symptoms and retinal scans, DNA samples are taken from LCA patients in order to test for the presence of the known gene mutations that cause LCA and, where possible, to identify the specific genetically defined disease, such as LCA10. If we, or any third parties that we engage to assist us, are unable to successfully identify such patients, or experience delays in doing so, then:

- our ability to develop any product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- any product candidates we develop may not receive marketing approval if safe and effective use of such product candidates depends on an *in vitro* diagnostic; and
- we may not realize the full commercial potential of any product candidates we develop that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines.

As a result, we may be unable to successfully develop and realize the commercial potential of any product candidates we may identify and develop, and our business, financial condition, results of operations, and prospects would be materially adversely affected.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate we develop, and any such approval may be for a more narrow indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if any product candidates we develop meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory

authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we develop. Any of the foregoing scenarios could materially harm the commercial prospects for any product candidates we develop and materially adversely affect our business, financial condition, results of operations, and prospects.

Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Ethical, social, and legal concerns about genomic medicines generally and genome editing technologies specifically could result in additional regulations restricting or prohibiting our products. Even if any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors, and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages compared to alternative treatments;
- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our medicines for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the European Commission, or other regulatory agencies;
- public attitudes regarding genomic medicine generally and genome editing technologies specifically;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, as well as their willingness to accept a therapeutic intervention that involves the editing of the patient's genome;
- product labeling or product insert requirements of the FDA, the EMA, or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength of marketing and distribution support;

- sufficient third-party coverage or reimbursement; and
- the prevalence and severity of any side effects.

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

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

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

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

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future medicines;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues or the profitability of these product revenues to us may be lower than if we were to market and sell any medicines we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our medicines effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The development and commercialization of new drug products is highly competitive. Moreover, the biotechnology and pharmaceutical industries, including in the gene therapy, genome editing and cell therapy fields, are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property and proprietary products. We will face competition with respect to any of our product candidates now and in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

Our platform and product focus is the development of therapies using CRISPR technology. Other companies developing CRISPR technology or therapies using CRISPR technology include Arbor Biotechnologies, Caribou Biosciences, CRISPR Therapeutics, ERS Genomics, Intellia Therapeutics, Locus Biosciences, ToolGen Inc. (“ToolGen”), TRACR Hematology and Vertex Pharmaceuticals. In addition, there have been and may continue to be discoveries of new CRISPR-based gene editing technologies. There are additional companies developing therapies using other genome editing technologies, including base editing, prime editing, transcription activator-like effector nucleases, meganucleases, Mega-TALs, and zinc finger nucleases. These companies include Beam Therapeutics, Prime Medicine, bluebird bio, Cellectis, Poseida Therapeutics, Precision Biosciences and Sangamo Therapeutics. Additional companies developing gene therapy products include Abeona Therapeutics, Adverum Biotechnologies, AGTC Therapeutics, Audentes Therapeutics, Homology Medicines, REGENXBIO, Sarepta Therapeutics, Solid Biosciences, Spark Therapeutics, uniQure and Voyager Therapeutics. In addition to competition from other genome editing therapies, gene therapies or cell medicine therapies, any products that we may develop may also face competition from other types of therapies, such as small molecule, antibody, protein, oligonucleotide, or ribonucleic acid therapies. For example, ProQR Therapeutics N.V. is conducting a clinical trial for its experimental treatment using antisense oligonucleotide technology for LCA10.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we develop against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of our

competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

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

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

Due to the novel nature of our technology and the potential for some of our product candidates to offer therapeutic benefit in a single administration or limited number of administrations, we face uncertainty related to pricing and reimbursement for these product candidates.

Our initial target patient populations for some of our programs are relatively small, as a result of which the pricing and reimbursement of any of our product candidates, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is

provided for services related to any of our product candidates, e.g., for administration of our product to patients, is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. In addition, it may be necessary for us to develop new reimbursement models in order to realize adequate value. Payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations, and prospects could be adversely affected.

We expect the cost of a single administration of genomic medicine products, such as those we are seeking to develop, to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any product candidates we develop will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers, and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several 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.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data. There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any of our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Moreover, the downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products such as ours. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any product candidates we develop will be harmed.

If the market opportunities for any of our product candidates are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer. Because the target patient populations for some of the product candidates we develop are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

Some of our most advanced programs, including EDIT-101, focus on treatments for rare genetically defined diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our products, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any medicines that we may develop.

We face an inherent risk of product liability exposure related to the testing in human clinical trials of any of our product candidates and will face an even greater risk if we commercially sell any medicines that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or medicines that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any medicines that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage if we successfully commercialize any medicine. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our commercial general liability and umbrella liability policies (under which we currently have an aggregate of $12.0 million in coverage) specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended,

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Genomic medicines are novel, and our product candidates may be complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization programs, limit the supply of our products, or otherwise harm our business.

Our product candidates will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as our product candidates generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. 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, or insufficient inventory. If we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA, and other 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 regulatory authorities may require that we not distribute a lot until the 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 or product recalls. Lot failures or product recalls could cause us to delay clinical trials, including the ongoing Phase 1/2 clinical trial for EDIT-101, or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects.

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

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of any product candidates we develop could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations, and prospects.

Any problems in our manufacturing process or the facilities with which we contract 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. Problems in third-party manufacturing process or facilities also could restrict our ability to ensure sufficient clinical material for any clinical

trials we may be conducting or are planning to conduct and meet market demand for any products we commercialize.

Risks Related to Our Dependence on Third Parties

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

We anticipate seeking third-party collaborators for the research, development, and commercialization of certain of the product candidates we develop or for development of certain of our research programs. Our likely collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them and, if applicable, whether they exercise any additional options to commercialize a product. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or any of our product candidates and alliance arrangements we may enter into under which our research programs or product candidates may be involved pose the following risks to us:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Collaborators with marketing and distribution rights to one or more medicines may not commit sufficient resources to the marketing and distribution of such medicine or medicines.
- Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.

- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.

For example, in March 2017, we entered into a strategic alliance with Allergan focused on discovering, developing, and commercializing new gene editing medicines for a range of ocular disorders, which collaboration was terminated in August 2020. As a result of the termination of the collaboration and the related co-development and commercialization agreement, we are now obligated to fund all of the costs related to developing and commercializing the LCA10 program in the United States, including the costs of the clinical development of EDIT-101, which will increase our expenses significantly.

If our collaborations do not result in the successful development and commercialization of products, or if one of our collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described in this Quarterly Report on Form 10-Q apply to the activities of our collaborators.

We may in the future decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of any of our product candidates. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement 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 several factors. If we license rights to any of our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our product development and research programs and the potential commercialization of any of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates and research programs, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates or programs.

We face significant competition in seeking appropriate collaborators. Whether we 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators or allies. For example, under our amended and restated collaboration with Juno Therapeutics, we may not use directly or indirectly, or license others to use, genome editing technology in connection with any research, development, manufacture, commercialization or other exploration of certain T cells, subject to certain exceptions, as more fully described in "Part I—Business—Our Collaborations and Licensing Strategy" of our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 26, 2020 (the "Annual Report"). Collaborations are also complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies, including the impending acquisition of Asklepios BioPharmaceutical, Inc. by Bayer AG, the acquisition of Allergan by AbbVie Inc. in May 2020, and the acquisition of Juno Therapeutics' parent entity, Celgene Corporation by Bristol-Myers Squibb Company, that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

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

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our clinical trials. We currently rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Additionally, the activities performed by these third parties may be delayed or suspended in light of the ongoing COVID-19 pandemic, which may impact our ability to successfully develop and test our product candidates and research programs in a timely manner.

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

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

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

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

We have a limited ability to manufacture materials for our research programs and preclinical studies and we do not operate any significant manufacturing facilities. We primarily rely on third-party contract manufacturing organizations ("CMOs") for the manufacture of our materials for preclinical and clinical studies and expect to continue to do so and for commercial supply of any product candidates that we develop and for which we or our collaborators obtain marketing approval. Additionally, the activities performed by our CMOs may be delayed or suspended in light of the ongoing COVID-19 pandemic, which may impact our ability to successfully develop and test our product candidates, including in clinical trials, and research programs in a timely manner.

Even though we have established supply agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or medicines, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business, financial condition, results of operations, and prospects.

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture any of our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

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

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any products we develop and for our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any of our product candidates, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States

and other countries with respect to our CRISPR platform technology and any proprietary product candidates and technology we develop. We seek to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications in the United States and abroad related to our technologies and product candidates that are important to our business. If we or our licensors and/or collaborators are unable to obtain or maintain patent protection with respect to our CRISPR platform technology and any proprietary products and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

No consistent policy regarding the scope of claims allowable in the field of genome editing, including CRISPR technology, has emerged in the United States. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

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

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

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, we are aware that third parties have suggested the use of the CRISPR technology in conjunction with a protein other than Cas9 or Cas12a. Our owned and in-licensed patents may not cover CRISPR technology in conjunction with a protein other than Cas9 or Cas12a. If our competitors commercialize the CRISPR technology in conjunction with a protein other than Cas9 or Cas12a, our business, financial condition, results of operations, and prospects could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Our licensors are currently, and we or our licensors may in the future become, subject to a third party pre-issuance submission of prior art to the United States Patent and Trademark Office (the "USPTO") or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings and other similar proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or

invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. As discussed below, some of our in-licensed patents are subject to interference, opposition and *ex parte* re-examination proceedings and therefore subject to these risks.

In addition, 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed patents and patent applications may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the U.S. government has certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention. For example, our licensors, including The Broad Institute, Inc. ("Broad"), have granted the U.S. government non-exclusive, non-transferable, irrevocable, paid-up licenses to practice or have practiced for or on behalf of the United States, the inventions described in certain of our in-licensed patents and patent applications, including certain aspects of our in-licensed CRISPR technology. If the government decides to exercise these rights, it is not required to engage us as its contractor in connection with doing so. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of any of the foregoing rights could harm our competitive position, business, financial condition, results of operations, and prospects.

Our rights to develop and commercialize our technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We are heavily reliant upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our genome editing technology, including our CRISPR technology, and product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. For example, pursuant to our license agreements with Broad, and Broad and the President and Fellows of Harvard College ("Harvard"), the licensors may, under certain circumstances, grant a license to the patents that are the subject of such license agreements to a third party. Such third party would have full rights to the patent rights that are the subject of such licenses, which could impact our

competitive position and enable a third party to commercialize products similar to our future product candidates and technology. Furthermore, under these license agreements, Broad has the right, after specified periods of time and subject to certain limitations, to designate gene targets for which Broad, whether alone or together with an affiliate or third party, has an interest in researching and developing products that would otherwise be covered by rights licensed to us under the agreements. Any of the foregoing would narrow the scope of our exclusive rights to the patents and patent applications we have in-licensed from Broad. The terms of these license agreements are described more fully under "Part I—Business—Our Collaborations and Licensing Strategy" in our Annual Report. In addition, our rights to our in-licensed patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. For example, pursuant to each of our intellectual property licenses with Broad, Harvard, and The General Hospital Corporation, d/b/a Massachusetts General Hospital, our licensors retain control of preparation, filing, prosecution, and maintenance, and, in certain circumstances, enforcement and defense of their patents and patent applications. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. Additionally, given that we are required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in-license from them, given the ongoing nature of the interference, opposition and re-examination proceedings involving the patents licensed to us under our license agreement with Harvard and Broad, and given that our obligation to make such reimbursements are not subject to any limitations, we anticipate that our obligation to reimburse our licensors for expenses related to these matters will continue to be substantial. In connection with these reimbursement obligations, we incurred expenses in aggregate amounts of $14.0 million, $14.2 million, and $18.7 million during the years ended December 31, 2019, 2018 and 2017, respectively, and we incurred expenses in an aggregate amount of $9.3 million during the nine months ended September 30, 2020.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-license. For example, certain patent applications licensed to us by Broad are co-owned with NIH. Broad does not and does not purport to grant any rights in NIH's interest in these patent applications under our agreement. If other third parties have ownership rights to our in-licensed patents and patent applications, they may be able to license such patents and patent applications to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Some of our in-licensed patents are subject to priority and validity disputes. In addition, our owned and in-licensed patents, patent applications and other intellectual property may be subject to further priority and validity disputes, and other similar intellectual property proceedings including inventorship disputes. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the product candidates we develop, which could have a material adverse impact on our business.

Certain U.S. patents (U.S. Patent Nos. 8,697,359; 8,771,945; 8,795,965; 8,865,406; 8,871,445; 8,889,356; 8,895,308; 8,906,616; 8,932,814; 8,945,839; 8,993,233; and 8,999,641) and a U.S. patent application (U.S. Serial No. 14/704,551) that are co-owned by Broad and the Massachusetts Institute of Technology ("MIT"), and in some cases Harvard, and in-licensed by us were involved in a first interference with a U.S. patent application (U.S. Serial No. 13/842,859, now U.S. Patent No. 10,266,850) that is co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier. An interference is a proceeding before the Patent Trial and Appeal Board of the USPTO ("PTAB") to determine priority of invention of the subject matter of patent claims filed by different parties.

During the preliminary motions phase of the proceeding, the PTAB held that there was no interference-in-fact, meaning that no interference was needed to resolve priority between the parties because the in-licensed claims are directed to subject matter that is patentably distinct from those of the University of California, the University of Vienna, and Emmanuelle Charpentier. The interference proceeding was therefore ended without reaching the priority phase. On appeal, the Court of Appeals for the Federal Circuit (the "CAFC") affirmed the PTAB's holding and the University of California, the University of Vienna, and Emmanuelle Charpentier did not appeal to the U.S. Supreme Court for review of this decision. The judgment of no interference-in-fact is therefore final and bars any further interference between the same parties for claims to the same invention that was considered in the interference. The invention that was considered in this first interference was related to a method that involves contacting a target DNA in a eukaryotic cell with certain defined CRISPR/Cas9 components for the purpose of cleaving or editing a target DNA molecule or modulating transcription of at least one gene encoded thereon.

As a result, the 12 U.S. patents and one U.S. patent application that we have in-licensed from Broad, acting on behalf of itself, MIT, and Harvard, with respect to which the PTAB had declared an interference were not modified or revoked as a result of this first interference proceeding. However, as discussed below, these 12 U.S. patents and one U.S. patent application are, and may in the future be, subject to further intellectual property proceedings and disputes, including interference proceedings.

On June 24, 2019, the PTAB declared a second interference between 10 pending U.S. patent applications (U.S. Serial No. 15/947,680; 15/947,700; 15/947,718; 15/981,807; 15/981,808; 15/981,809; 16/136,159; 16/136,165; 16/136,168; and 16/136,175) that are co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier and the same 12 U.S. patents and one U.S. patent application involved in the first interference that are co-owned by Broad and MIT, and in some cases Harvard, and in-licensed by us. One additional U.S. patent (U.S. Patent No. 9,840,713) that is co-owned by Broad and MIT and in-licensed by us and not involved in the first interference is also included in this second interference. On August 26, 2019, the PTAB re-declared the interference to add four pending U.S. patent applications (U.S. Serial No. 16/276,361; 16/276,365; 16/276,368; and 16/276,374) that are co-owned by the University of California, the University of Vienna, and Emmanuelle Charpentier. The declaration of interference described the interfering subject matter as related to a eukaryotic cell that comprises a target DNA and certain defined CRISPR/Cas9 components including a single-molecule guide RNA that are capable of cleaving or editing the target DNA molecule or modulating transcription of at least one gene encoded thereon.

On September 10, 2020, the PTAB granted Broad's motion for priority benefit while denying the University of California, the University of Vienna, and Emmanuelle Charpentier priority benefit to their two earliest provisional patent applications. As a result, Broad will enter the priority phase of the interference as "Senior Party" while the University of California, the University of Vienna, and Emmanuelle Charpentier remain the "Junior Party" for purposes of determining which entity was the first to invent the inventions at issue. Although we cannot predict with any certainty how long the second interference will actually take, it may take approximately a year or longer before the PTAB issues a decision at the conclusion of the priority phase. It also remains possible that other third parties may seek to become a

party to this interference.

The University of California, the University of Vienna, and Emmanuelle Charpentier or other third parties may file a separate Suggestion of Interference against the Broad patents and patent application that are subject to the interference or other U.S. patents and patent applications that we own or in-license. For example, ToolGen filed Suggestions of Interference in the USPTO on April 13, 2015 suggesting that they believe some of the claims in pending U.S. applications owned by ToolGen (U.S. Serial No. 14/685,568 and U.S. Serial No. 14/685,510) interfere with certain claims in five U.S. patents, which we have in-licensed from Broad, acting on behalf of itself, MIT, and Harvard. These five U.S. patents are among the 13 U.S. patents with respect to which the PTAB has declared a second interference. The Suggestions of Interference that were filed by ToolGen are still pending and it is uncertain when and in what manner the USPTO will act on them.

Our owned and in-licensed patents and patent applications are, or may in the future become, subject to validity disputes in the USPTO and other foreign patent offices. For example, a request for *ex parte* re-examination was filed with the USPTO on February 16, 2016 against one U.S. patent that we have in-licensed from Broad, acting on behalf of itself and MIT (U.S. Patent No. 8,771,945), which is part of the second interference and referenced in the Suggestions of Interference filed by ToolGen. *Ex parte* re-examination is a procedure through which a third party can anonymously request the USPTO to re-examine a granted patent because the third party believes the granted patent may not be patentable over prior art in the form of a printed publication or another patent. Before the USPTO will re-examine a granted patent, the third party requestor must establish that the submitted prior art establishes a substantial and new question of patentability. If the USPTO determines there is a substantial and new question of patentability, it grants the re-examination request and re-examines the patent after giving the patent owner the option of filing an initial statement. The request for *ex parte* re-examination of U.S. Patent No. 8,771,945 was granted on May 9, 2016 thereby initiating a re-examination procedure between the USPTO and Broad, acting on behalf of itself and MIT. The third party requestor does not participate in the re-examination procedure after filing the request except that it has the option of responding if the patent owner chooses to file an initial statement. On May 12, 2016, the PTAB suspended the re-examination noting that it has jurisdiction over any file that involves a patent involved in an interference. On January 3, 2019, the PTAB lifted the suspension in light of the CAFC's affirmance of the PTAB's no interference-in-fact holding in the first interference. On June 24, 2019, when the PTAB declared the second interference it re-suspended the re-examination. It is uncertain when the PTAB will lift the suspension. If Broad is unsuccessful during the re-examination, U.S. Patent No. 8,771,945 may be revoked or narrowed, which could have a material adverse effect on the scope of our rights under such patent.

The 13 in-licensed U.S. patents and one in-licensed U.S. patent application that are the subject of the second interference (which includes the five in-licensed U.S. patents that are the subject of the Suggestions of Interference filed by ToolGen and the one in-licensed U.S. patent that is the subject of the re-examination) relate generally to the CRISPR/Cas9 system and its use in eukaryotic cells. The claims of the 13 in-licensed U.S. patents and one in-licensed U.S. patent application vary in scope and coverage and include claims that are directed to CRISPR/Cas9 systems that employ viral vectors for delivery, single guide RNAs, modified guide RNAs, *S. aureus* Cas9, or a Cas9 nickase and are relevant to our genome editing platform technology. The loss or narrowing in scope of one or more of these in-licensed patents could have a material adverse effect on the conduct of our business, financial condition, results of operations, and prospects.

We or our licensors may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned or in-licensed patents or patent applications, or other intellectual property rights as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents, patent applications or other intellectual property rights, such co-owners may be able to license their rights to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any patents, including any patents that issue from patent applications, against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on the conduct of our business, financial condition, results of operations, and prospects.

We or our licensors are subject to and may in the future become a party to similar proceedings or priority disputes in Europe or other foreign jurisdictions. For example, four European patents that we have in-licensed from

Broad, acting on behalf of itself and MIT, or itself, MIT and Harvard (European Patent Nos. EP 2,764,103 B1, EP 2,771,468 B1, EP 2,784,162 B1, and EP 2,931,898 B1) have been revoked in their entirety by the European Patent Office Opposition Division (the "Opposition Division"). Broad, acting on behalf of itself and MIT, or itself, MIT and Harvard filed notices of appeal to the Boards of Appeal of the EPO for review of the Opposition Division's decisions to revoke these four patents. On January 16, 2020, the Boards of Appeal dismissed the appeal filed for European Patent No. 2,771,468 B1, which means this European patent remains revoked in its entirety. On January 30, 2020, Broad acting on behalf of itself, MIT and Harvard withdrew the appeal filed for European Patent No. EP 2,931,898 B1, which means this European patent will remain revoked in its entirety. It is uncertain when or in what manner the Boards of Appeal will act on the two remaining appeals. Three other European patents that we have in-licensed from Broad, acting on behalf of itself, MIT and Harvard (European Patent Nos. EP 2,896,697 B1, EP 2,898,075 B1, and EP 3,009,511 B1) were maintained with amended patent claims. Broad, acting on behalf of itself, MIT and Harvard filed notices of appeal to the Boards of Appeal of the EPO for review of the Opposition Division's decisions to maintain European Patent No. EP 2,896,697 B1 and EP 2,898,075 B1 with amended patent claims. Two of the opponents also filed notices of appeal for European Patent No. EP 2,896,697 B1 and EP 2,898,075 B1. It is uncertain when or in what manner the Boards of Appeal will act on these appeals. The Opposition Division has also initiated opposition proceedings against nine other European patents that we have in-licensed from Broad, acting on behalf of itself and MIT, or itself, MIT and Harvard, or itself, MIT, Harvard and The Rockefeller University ("Rockefeller") (European Patent Nos. EP 2,825,654 B1, EP 2,840,140 B1, EP 2,921,557 B1, EP 2,931,892 B1, EP 2,931,897 B1, EP 2,940,140 B1, EP 3,011,032 B1, EP 3,011,034 B1, and EP 3,494,997 B1), and one European patent that we co-own and in-license from Broad, acting on behalf of itself, MIT and The University of Iowa Research Foundation (European Patent No. EP 3,066,201 B1). The EPO opposition proceedings may involve issues including, but not limited to, procedural formalities related to filing the European patent application, priority, and the patentability of the involved claims. The loss of priority for, or the loss of, these European patents could have a material adverse effect on the conduct of our business. One or more of the third parties that have filed oppositions against these European patents or other third parties may file future oppositions against other European patents that we in-license or own. For example, we are aware that oppositions have been filed against three European patents that we have in-licensed from Broad, acting on behalf of itself, MIT and Harvard (European Patent Nos. EP 3,064,585 B1, EP 3,144,390 B1, and EP 3,310,917). The deadlines for filing oppositions against these European patents are November 5, 2020, December 18, 2020 and November 12, 2020, respectively. There may be other oppositions against these European patents that have not yet been filed or that have not yet been made available to the public.

If we or our licensors are unsuccessful in any patent related disputes, including interference proceedings, patent oppositions, re-examinations, or other priority, inventorship, or validity disputes to which we or they are subject (including any of the proceedings discussed above), we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents and patent applications. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we develop. The loss of exclusivity or the narrowing of our owned and in-licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in any interference proceeding or other priority, inventorship, or validity disputes, it could result in substantial costs and be a distraction to our management and other employees.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. For example, certain U.S. patent applications licensed to us by Broad include The University of Tokyo ("Tokyo") and NIH

as joint applicants. Broad has only granted a license to us with respect to its interests and to Tokyo's interests in these U.S. patent applications but not to any foreign equivalents thereof. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We have entered into license agreements with third parties and may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates,

or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, including CRISPR genome editing technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

In each of our license agreements, and we expect in our future agreements, we are responsible for bringing any actions against any third party for infringing on the patents we have licensed. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

We may not be successful in obtaining necessary rights to any product candidates we develop through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. Many pharmaceutical companies, biotechnology companies, and academic institutions are competing with us in the field of genome editing technology and filing patent applications potentially relevant to our business. For example, we are aware of third party patents and patent applications that may be construed to cover our CRISPR technology and product candidates. In order to avoid infringing these third party patents, or patents that issue from these third party patent applications, we may find it necessary or prudent to obtain licenses from such third party intellectual property holders. We may also require licenses from third parties for certain non-CRISPR technologies including certain delivery methods that we are evaluating for use with product candidates we develop. In addition, with respect to any patents we co-own with third parties, we may require licenses to such co-owners' interest in such patents.

However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our CRISPR technology and product candidates we develop. The licensing or acquisition of third party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. For example, certain methods for editing cells, guide RNA modifications and delivery modes, including certain adeno-associated virus vector technologies, that we are evaluating for use are covered by patents held by third parties. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act") enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

If we or one of our licensors or our collaborators were to initiate legal proceedings against a third party to enforce a patent covering a product candidate we develop or our technology, including CRISPR genome editing technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties have raised challenges to the validity of certain of our in-licensed patent claims and may in the future raise similar claims before administrative bodies in the United States or abroad, even

outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). For example, as discussed above, 13 of our in-licensed U.S. patents and one of our in-licensed U.S. patent applications are involved in an interference, and Suggestions of Interference have been filed against certain of our in-licensed U.S. patents, one of these U.S. patents is subject to a re-examination proceeding, opposition proceedings have been initiated against several of our in-licensed European patents and additional interference, re-examination, post-grant review, *inter partes* review, opposition, and other intellectual property proceedings may be initiated in the future. The opposition proceedings have so far resulted in the revocation of four of our in-licensed European patents while maintaining three of our in-licensed European patents with amended claims. In view of certain arguments made by the third parties against the revoked patents and similar arguments made by the third parties against other in-licensed European patents under opposition, and in view of the Boards of Appeal's dismissal of the appeal filed for European Patent No. 2,771,468 B1, the opposition proceedings will likely lead to the revocation of additional in-licensed European patents. These and other proceedings could result in the revocation or cancellation of, or amendment to our patents in such a way that they no longer cover our technology or platform, or any product candidates that we develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

The intellectual property landscape around genome editing technology, including CRISPR, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

The field of genome editing, especially in the area of CRISPR technology, is still in its infancy, and no such products have reached the market. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market, and sell any product candidates that we develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We are subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any product candidates we develop, including interference, re-examination, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. We are aware of certain third party patents and patent applications in this landscape that may be asserted to encompass our CRISPR/Cas9 technology. In particular, we are aware of several separate families of U.S. patents and/or U.S. patent applications and foreign counterparts which relate to CRISPR/Cas9 technology, where the earliest priority dates of each family pre-date the priority dates of our in-licensed patents and patent applications, including PCT Publication No. WO 2013/141680 (and its related U.S. Patent No. 9,637,739 and other related U.S. patent applications and foreign counterparts including European Patent No. EP 2,828,386 B1, which is being opposed by at least one party) filed by Vilnius University (which is reported to have exclusively licensed its rights to DuPont Pioneer, which is reported to have licensed certain rights to Caribou Biosciences, which is reported to have non-exclusively licensed certain rights to Intellia Therapeutics and CRISPR Therapeutics), WO 2013/176772 (and its related U.S. Patents including U.S. Patent Nos. 10,000,772, 10,113,167, 10,227,611, and 10,266,850, 10,301,651, 10,308,961, 10,337,029, 10,351,878, 10,358,658, and 10,358,659 among others, and other related U.S. patent applications and foreign counterparts including European Patent Nos. EP 2,800,811 B1, EP 3,241,902 B1, and EP 3,401,400 B1 which are being opposed by several parties) filed by the University of California, the University of Vienna (both of which are reported to

have exclusively licensed their rights to Caribou Biosciences, which is reported to have exclusively licensed certain rights to Intellia Therapeutics), and Emmanuelle Charpentier (who is reported to have exclusively licensed her rights to CRISPR Therapeutics, ERS Genomics and TRACR Hematology), WO 2014/065596 (and its related U.S. Patent Nos. 10,731,181 and 10,745,716, and other related U.S. patent applications and foreign counterparts including European Patent No. EP 2,912,175 B1 which is being opposed by several parties) filed by ToolGen, and WO 2014/089290 (and its related U.S. patent applications and foreign counterparts including European Patent Nos. EP 2,928,496 B1, EP 3,138,910 B1, EP 3,138,911 B1, EP 3,138,912 B1, EP 3,360,964 B1 and EP 3,363,902 B1, which are being opposed by several parties) filed by Sigma-Aldrich Co. LLC. Each of these patent families are owned by a different third party and contain claims that may be construed to cover components and uses of CRISPR/Cas9 technology. If we are not able to obtain or maintain a license on commercially reasonable terms to any third-party patents that cover our product candidates or activities, such third parties could potentially assert infringement claims against us, which could have a material adverse effect on the conduct of our business.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any product candidates we develop and any other product candidates or technologies covered by the asserted third party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any product candidates we develop and our 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 and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

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

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

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

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

Competitors may infringe our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also are, and may in the future become, involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of any of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Any of our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biologic product candidate's safety, purity, and potency. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any of our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved medicine not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any of our product candidates, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent any of our product candidates from being marketed in such jurisdictions, which, in turn, would materially impair our ability to generate revenue.

In order to market and sell any of our product candidates in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United

States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our medicines in any jurisdiction, which would materially impair our ability to generate revenue.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020, with a transitional period until December 31, 2020. Discussions between the United Kingdom and the European Union are ongoing and are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the transitional period. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption

Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

Even if we, or any collaborators we may have, obtain marketing approvals for any of our product candidates, the terms of approvals and ongoing regulation of our products could require the substantial expenditure of resources and may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such medicine, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the medicine may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine.

Accordingly, assuming we, or any collaborators we may have, receive marketing approval for one or more of our product candidates, we, and such collaborators, and our and their contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we and such collaborators are not able to comply with post-approval regulatory requirements, we and such collaborators could have the marketing approvals for our products withdrawn by regulatory authorities and our, or such collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our business, operating results, financial condition, and prospects.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our medicines, when and if any of them are approved.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our medicines for their approved indications, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. Violation of the Federal Food, Product, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may also lead to

investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown problems with our medicines, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such medicines, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine;
- requirements to conduct post-marketing clinical trials;
- receipt of warning or untitled letters;
- withdrawal of the medicines from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of medicines;
- fines, restitution, or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our medicines;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations, and prospects.

Our relationships with healthcare providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any of our product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of,

any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996, as further amended by the Health Information Technology for Economic and Clinical Health Act, which imposes certain requirements, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses, and health care providers;

- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The efforts of the current presidential administration to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

The current presidential administration has taken 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, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, the 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 interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. The president has also issued an executive order meant to ensure that agency guidance documents do not establish legally binding requirements and it directs each agency to rescind guidance documents that it determines should no longer be in effect. 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.

Recently enacted and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Modernization Act"), changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in

payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "PPACA"), which became law in 2010, contains provisions of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of federal healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA 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. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Since enactment of the PPACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (the "TCJA"), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the PPACA, effective January 1,

2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress may in the future consider other legislation to replace elements of the PPACA.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our potential products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

There has been significant litigation relating to the PPACA. Most recently, in March 2020, the U.S. Supreme Court agreed to hear a case relating to a ruling by a U.S. District Court judge in the Northern District of Texas that the individual mandate portion of the PPACA is an essential and inseverable feature of the PPACA and, therefore, because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the PPACA are invalid as well; the Court of Appeals for the Fifth Circuit affirmed the lower court ruling. On June 25, 2020, the Trump Administration and a coalition of 18 states asked the court to strike down the entirety of the PPACA. The case is scheduled for oral argument before the court on November 10, 2020. It is unclear how such litigation and other efforts to repeal and replace the PPACA will impact the PPACA and our business.

The current presidential administration has also taken executive actions to undermine or delay implementation of the PPACA. Since January 2017, the president has signed two executive orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. One executive order directs federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second executive order terminates the cost-sharing subsidies that reimburse insurers under the PPACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the PPACA for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in PPACA risk corridor payments to third-party payors who argued were owed to them. This decision has recently been overturned by the U.S. Supreme Court.

The costs of prescription pharmaceuticals has also been the subject of considerable discussion in the United States, and members of Congress and the executive branch have stated that they will address such costs through new legislative and administrative measures. To date, there have been several U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the current presidential administration has pressed for enactment of a number of drug price control measures, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the current presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Finally, the current presidential administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs.

More recently, the president issued five executive orders that are intended to lower the costs of prescription drug products. The first order would require all federally qualified health centers ("FQHCs") to pass on to patients the

discounts the health centers receive on insulin and epinephrine through Medicare's 340B Drug Discount Program. The second order would establish an international pricing index that would set the price Medicare Part B pays for the costliest medications covered under the program to the lowest price in other economically advanced countries.

The third order is intended to reduce the costs of drugs by supporting the safe importation of prescription drugs. Specifically, the order calls upon the Department of Health and Human Services ("HHS") to facilitate grants to individuals of waivers of the prohibition of importation of prescription drugs that would allow patients to import FDA approved drug products from abroad, so long as doing so would result in lower costs. In addition, the order would allow wholesalers and pharmacies to re-import both biological drugs and insulin that were originally manufactured in the United States and then exported for international sale. This action preceded the finalization of a rulemaking on September 24, 2020 that allows states or certain other non-federal government entities to submit importation program proposals to the FDA for review and approval. Applicants would be required to demonstrate that their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, the FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

The fourth executive order would end drug rebates used by health plan sponsors, pharmacies or pharmacy benefit managers ("PBMs") in operating the Medicare Part D program. Specifically, the order directs HHS to exclude from safe harbor protections under the federal anti-kickback statute retroactive price reductions that are not applied at the point-of-sale. Instead, the order requires HHS to establish new safe harbors that would allow health plan sponsors, pharmacies, and PBMs to pass on those discounts to consumers at point-of-sale in order to lower the patient's out-of-pocket costs and permit the use of certain bona fide PBM service fees. Each of these orders directs the federal government to implement the initiatives outlined in the orders, meaning they will not have immediate effects.

Finally, the fifth order instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including especially China. The order is meant reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates.

If a product candidate is intended for the treatment of a serious or life threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. However, a fast track designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while we may seek and receive fast track designation for our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Priority review designation by the FDA may not lead to a faster regulatory review or approval process and, in any event, does not assure FDA approval of our product candidates.

If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for certain of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

We may not be able to obtain orphan drug exclusivity for one or more of our product candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA has issued recent draft guidance suggesting that it would not consider two gene therapy products to be different drugs solely based on minor differences in the transgenes or vectors. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 (“FDARA”). FDARA, among other things, codified the FDA’s pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants,

and partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission, and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or 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, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S.

exchanges for violations of the FCPA's accounting provisions.

Risks Related to Employee Matters, Managing Growth, Public Health and Information Technology

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

We are highly dependent on the principal members of our management and scientific teams. Each of these individuals is employed "at will," meaning we or the individual may terminate the employment relationship at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. Additionally, we are actively trying to recruit a candidate for the role of Chief Medical Officer. Any inability to fill this position in an expedient manner may have a material adverse effect on our business.

Recruiting and retaining qualified scientific, clinical, manufacturing, and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. 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. The inability to recruit or loss of services of certain executives, including a Chief Medical Officer, other key employees, consultants, or advisors may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects.

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, including the COVID-19 pandemic, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.

Significant outbreaks of contagious diseases, and other adverse public health developments, could have a material impact on our business operations and operating results. For example, the spread of COVID-19 has affected segments of the global economy and could affect our operations. We have taken steps in line with guidance from the U.S. Centers for Disease Control and Prevention, the Commonwealth of Massachusetts and the State of Colorado, the jurisdictions in which we primarily operate our business, to protect the health and safety of our employees and the community. In particular, we have implemented a work from home policy, and restricted on-site activities at our facilities in Massachusetts and Colorado to certain manufacturing, laboratory and related support activities. Under our return-to-work plans, we have resumed manufacturing, laboratory, and related support activities at our facilities in Massachusetts and Colorado using shifts and other capacity-limiting measures to comply with social distancing guidelines. We continue to assess the impact of the COVID-19 pandemic to best mitigate risk and continue the operations of our business.

As a result of the COVID-19 pandemic or similar public health crises that may arise, we may experience disruptions that could adversely impact our operations, research and development, including preclinical studies, clinical trials and manufacturing activities, including:

- delays or disruptions in clinical trials that we may be conducting, including patient screening, patient enrollment, patient dosing, clinical trial site activation, and study monitoring;
- delays or disruptions in preclinical experiments and IND- and clinical trial application-enabling studies due to restrictions related to our staff being on site;
- interruption or delays in the operations of the FDA, EMA and comparable foreign regulatory agencies;

- interruption of, or delays in, receiving, supplies of drug substance and drug product from our CMOs or delays or disruptions in our pre-clinical experiments or clinical trials performed by CROs due to staffing shortages, production and research slowdowns or stoppages and disruptions in delivery systems or research;

- limitations imposed on our business operations by local, state, or federal authorities to address such pandemics or similar public health crises could impact our ability to conduct preclinical or clinical activities, including conducting IND- and CTA-enabling studies or our ability to select future development candidates; and

- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

For example and in light of the ongoing COVID-19 pandemic, we have decided to delay the development of our research program to treat autosomal dominant retinitis pigmentosa 4 and not to pursue declaring a development candidate for such program by the end of 2020. We have also recently experienced slowed enrollment in the EDIT-101 clinical trial as a result of the COVID-19 pandemic and may experience a further enrollment slowdown in light of the pandemic's current resurgence. In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising additional capital through sales of our common stock or such sales may be on unfavorable terms.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

We have expanded and expect to further expand our development, regulatory, clinical, manufacturing and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, clinical development, manufacturing, and sales and marketing. For example, our total number of employees grew from 132 as of January 1, 2019 to 208 as of February 1, 2020. 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 effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical 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 plans or disrupt our operations.

Security breaches and other disruptions to our information technology structure could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, as well as our proprietary business information and that of our suppliers and business partners, employee data, and we may collect personally identifiable information of clinical trial participants in connection with clinical trials. We also rely to a large extent on information technology systems to operate our business, including our financial systems. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to

our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is important to our operations and business strategy. Despite our security measures, our information technology infrastructure (and those of our partners, vendors and third-party providers) may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors, and other third-party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. While we have invested in information technology security measures and the protection of confidential information, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruptions or breach may substantially impair our ability to operate our business and would compromise our, and their, networks and the information stored could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Risks Related to Our Common Stock

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

Our shares of common stock began trading on The Nasdaq Global Select Market in February 2016. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

The market price of our common stock may be volatile, which could result in substantial losses for our stockholders.

Our stock price has been, and is likely to remain, volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for EDIT-101 and any preclinical studies and clinical trials of any other product candidates that we develop;
- commencement or termination of collaborations for our product development and research programs;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- developments or changing views regarding the use of genomic medicines, including those that involve genome editing;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs, or product candidates that we develop;

- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions, including the impact of the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

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

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

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

A portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a significant number of shares of our 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.

We have registered substantially all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, certain of our employees, executive officers, directors, and affiliated stockholders have entered or may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a

Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the participant establishing the plan when entering into the plan, without further direction from such participant. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our employees, executive officers, directors, and affiliated stockholders also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

We incur increased 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 we have incurred, and will continue to incur, significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select 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. We have had to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to SOX Section 404, we are required to furnish a report by our management on our internal control over financial reporting and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with SOX Section 404, we will continue to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to dedicate internal resources, engage outside consultants, 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. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by SOX Section 404. 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 consolidated financial statements.

We have broad discretion in the use of our cash reserves and may not use them effectively.

Our management has broad discretion to use our cash reserves and could use our cash reserves 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 their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

We do not expect to pay any dividends for the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investments.

We have never declared or paid cash dividends on our common 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 stockholders' sole source of gain for the foreseeable future.

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

Provisions in our restated certificate of incorporation and amended and restated bylaws or Delaware law may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- a classified board of directors so that not all members of our board of directors are elected at one time;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the requirement that at least 75% of the votes cast by all our stockholders approve the amendment or repeal of certain provisions of our amended and restated bylaws or restated certificate of incorporation;
- the ability of our board of directors to make, alter, or repeal our amended and restated bylaws; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a rights plan, or a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

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

The existence of the foregoing provisions could deter potential acquirers of our company, thereby reducing the likelihood that our stockholders could receive a premium for their shares of common stock in an acquisition.

Our restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors and officers.

Our restated certificate of incorporation provides that, unless our board of directors otherwise determines, the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to our company or our stockholders, any action asserting a claim against us or any of our directors or officers arising pursuant to any provision of the General Corporation Law of the State of Delaware or our restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us or any of our directors or officers governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act of 1934, which provides for exclusive jurisdiction of the federal courts. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended (the

"Securities Act"), inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder; provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 6. Exhibits

Exhibit Index

Exhibit Number	Description of Exhibit
10.1*†	Termination Agreement, dated August 5, 2020, by and between the Company and Allergan Sales, LLC.
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. §1350
101*	The following financial statements from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets (unaudited), (ii) Consolidated Statements of Operations (unaudited), (iii) Consolidated Statements of Comprehensive Income (Loss) (unaudited), (iv) Consolidated Statement of Stockholders' Equity (unaudited), (v) Consolidated Statements of Cash Flows (unaudited)and (vi) Notes to Condensed Consolidated Financial Statements (unaudited), tagged as blocks of text and including detailed tags.
104*	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, formatted in Inline XBRL.

*Filed herewith

† Confidential portions of this exhibit have been omitted.

+ The certifications furnished in Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications are not to be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates them by reference.

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.

EDITAS MEDICINE, INC.

Dated: November 6, 2020

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

EXECUTION VERSION

Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

TERMINATION AGREEMENT

This **TERMINATION AGREEMENT** (this "**Agreement**") is entered into on August 5, 2020 (the "**Effective Date**") by and between **Editas Medicine, Inc.**, a Delaware corporation ("**Editas**"), and **Allergan Sales, LLC**, a Delaware limited liability company ("**Allergan**"). Allergan and Editas are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

A. Editas and Allergan Pharmaceuticals International Limited, a private company limited by shares incorporated under the laws of Ireland and an Affiliate of Allergan ("**APIL**"), are parties to that certain Strategic Alliance and Option Agreement, dated March 14, 2017 (the "**Collaboration Agreement**"), pursuant to which (i) Editas and APIL established an alliance to discover, develop, and commercialize novel genomic medicines for ocular disorders, and (ii) Editas granted APIL an exclusive option to obtain an exclusive license as to certain Collaboration Development Programs and all Licensed Products arising therefrom, exercisable at APIL's sole discretion (each an "**Option**");

B. On July 19, 2018, APIL exercised its Option with respect to the LCA10 Program;

C. Concurrently with the Option exercise, APIL entered in that certain License Agreement, dated as of July 19, 2018, with Allergan (the "**Intercompany License**"), pursuant to which APIL sublicensed APIL's rights and obligations under the Collaboration Agreement with respect to the LCA10 Program to Allergan;

D. On August 3, 2018, Editas exercised its option under the Collaboration Agreement to participate with APIL in the profits and losses resulting from Development and Commercialization of Licensed Products resulting from the LCA10 Program in the United States;

E. On February 22, 2019, Allergan and Editas entered into a Co-Development and Commercialization Agreement (the "**Profit-Sharing Agreement**") to co-develop and share in the costs and certain responsibilities of Development of all Licensed Products arising from the LCA10 Program (the "**LCA10 Products**") in the United States and the profits and losses resulting from Commercialization of all LCA10 Products in the United States;

F. On May 27, 2019, APIL and Editas entered into a Master Services Agreement (the "**MSA**") to establish the terms and conditions governing the provision and results of the Services;

G. On August 4, 2020 APIL assigned all of its rights and obligations under the Collaboration Agreement and the MSA to Allergan;

H. The Parties now wish to terminate the Collaboration Agreement in its entirety and return to Editas the rights to all Licensed Products, on the terms and conditions set forth herein;

I. Allergan and APIL terminated the Intercompany License, effective on August 4; 2020;

J. Simultaneously with the termination of the Collaboration Agreement, the Parties also wish to terminate the Profit-Sharing Agreement and the MSA; and

K. Concurrently with the execution of this Agreement, the Parties are entering into a Transition Services Agreement (the "**TSA**") for the provision of certain transition services by Allergan to Editas.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Editas and Allergan hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement, and all other capitalized terms not otherwise defined herein shall have the meanings ascribed to them in the Collaboration Agreement:

1.1 "**Affiliate**" means any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "**control**" another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

1.2 "**Allergan Know-How**" means all Know-How that is (a) Controlled by Allergan or its Affiliates as of the Effective Date, (b) not publicly disclosed, (c) subject to confidentiality obligations, (d) necessary and material for the Development, Manufacture, or Commercialization of the Existing Compound and actually used or applied by Editas or its Affiliates to Develop, Manufacture or Commercialize the Existing Compound, and (e) developed solely or jointly by or on behalf of Allergan in the course of activities conducted pursuant to the LCA10 Program, but excluding any Know-How that prior to May 8, 2020 was Controlled by a Person that was not at that time an Affiliate of Allergan.

1.3 "**Allergan Patents**" means Allergan CDP Patents and Allergan's ownership interest in Joint CDP Patents.

1.4 "**Business Day**" means a day on which banking institutions in Boston, Massachusetts, United States are open for business, excluding any Saturday or Sunday.

1.5 "**Calendar Quarter**" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively.

1.6 "**Calendar Year**" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31.

1.7 "**Claims**" means all Third Party suits, claims, actions, proceedings or demands.

1.8 "**Collaboration Program Targets**" means LCA10, [**], [**] and [**].

1.9 "**Commercialization**" and "**Commercialize**" means all activities undertaken relating to the marketing, promotion (including advertising, detailing, sponsored product or continuing medical education), any other offering for sale, distribution, and sale of a product.

1.10 "**Commercially Reasonable Efforts**" means (a) with respect to the efforts to be expended by a Party with respect to an agreed objective, except as otherwise provided in clause (b), such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances taking into account the responsible allocation of such Party's resources under the circumstances, and (b) with respect to Editas' obligations [**].

1.11 "**Confidential Information**" of a Party means all Know-How, unpublished patent applications and other non-public information and data of a financial, commercial, business, operational or technical nature of such Party that is disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, in each case in connection with this Agreement, the Collaboration Agreement, the Profit-Sharing Agreement or the MSA, whether made available orally, visually, in writing or in electronic form.

1.12 "**Control**," "**Controls**," "**Controlled**" or "**Controlling**" means, with respect to any intellectual property, possession of the right (whether through ownership or license (other than by operation of this Agreement) or control over an Affiliate with such right) to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party.

1.13 "**Cover**," "**Covering**" or "**Covered**" means, with respect to a product, composition, technology, process or method that, in the absence of ownership of or a license granted under a Patent, the manufacture, use (where such use is for the treatment of an indication approved by the applicable Regulatory Authority), offer for sale, or sale of such product or composition would infringe such Patent (or, in the case of a Patent that has not yet issued, would infringe such Patent if it were to issue).

1.14 "**CRISPR**" means a clustered regularly interspaced short palindromic repeat.

1.15 "**CRISPR Technology**" means an enzymatically active or inactive Cas9, Cpf1 or other CRISPR-derived endonuclease and one or more nucleic acid sequence(s).

1.16 "**Deliverables**" means anything required to be provided by Allergan to Editas under the MSA.

1.17 "**Develop**" or "**Development**" means all activities relating to research, non-clinical and preclinical testing and trials, clinical testing and trials, including clinical trials, toxicology

testing, modification, optimization and animal efficacy testing of pharmaceutical compounds, statistical analysis, publication and presentation of study results and reporting, preparation and submission to Regulatory Authorities of applications (including any CMC information) relating to Editas Products.

1.18 "**Dollars**" or "**$**" means the legal tender of the U.S.

1.19 "**Editas Product**" means any Gene Editing Therapy, including any Gene Editing Therapy that includes the Existing Compound, Developed by Editas, its Affiliates, Licensees, or Sublicensees, that modifies a Collaboration Program Target.

1.20 "**Editas Program**" means the Development programs for each Collaboration Program Target undertaken by Editas, its Affiliates, Licensees, or Sublicensees.

1.21 "**EMA**" means the European Medicines Agency, and any successor entity thereto.

1.22 "**European Union**" means (a) the European Union and its member states as of the Effective Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxemburg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden, and (b) the United Kingdom, Norway, Iceland, Liechtenstein, Andorra, Monaco, San Marino and the Vatican, and each of their successors to the extent such successors occupy the territory included in each such jurisdiction. For clarity, any of the named countries in subsection (a) shall remain part of the European Union for the purpose of this Agreement regardless of whether they remain a member state of the European Union.

1.23 "**Existing Compound**" means AGN-151587/EDIT-101.

1.24 "**FDA**" means the U.S. Food and Drug Administration and any successor entity thereto.

1.25 "**Field**" means a category of human diseases or conditions affecting the same therapeutic area.

1.26 "**First Commercial Sale**" means, with respect to an Editas Product and a country, the first sale of such Editas Product made by Editas, its Affiliates, Licensees, or Sublicensees to a Third Party in such country for end use or consumption in such country after any necessary Regulatory Approval and, with respect to the European Union, separate pricing approval (but, for clarity, excluding any sales for clinical trials or compassionate use programs).

1.27 "**FTE Rate**" means US$[**] per year (consisting of at least a total of [**] hours per Calendar Year of work).

1.28 [**]

1.29 "**GAAP**" means U.S. generally accepted accounting principles, consistently applied.

1.30 "**Gene Editing Therapy**" means a product that uses Genome Editing Technology that functions through a mechanism of action of (a) editing (including modifying) of Genetic Material or (b) targeting of Genetic Material (including targeting of Genetic Material to modify associated chromatin), either (i) ex vivo for subsequent administration to a human, in the case of the foregoing clause (a) or (b) of a product so edited or targeted, or (ii) in vivo, by a product administered to a human, in the case of the foregoing clause (a) or (b) of a product that so edits or targets.

1.31 "**Genetic Material**" means all DNA (including DNA in and outside chromosomes) and RNA.

1.32 "**Genome Editing Technology**" means any CRISPR Technology, zinc finger nuclease, transcription activator-like effector nucleases (TALEN), or any other therapeutic endonuclease genome editing technology.

1.33 **"Governmental Authority**" means any United States federal, state or local or any foreign government, or political subdivision thereof, or any multinational organization or authority or any authority, agency, division, board or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.34 "**Know-How**" means any ideas, Inventions, know-how, trade secrets, data, specifications, instructions, processes, formulas, technology, expert opinions and information, including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data or information. For clarity, Know-How excludes such information disclosed in published Patents.

1.35 "**Law**" means all laws, statutes, rules, regulations, treaties, orders, judgments, or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

1.36 "**LCA10**" means any disease caused by a mutation in or around the CEP290 gene.

1.37 "**LCA10 Program**" means the Collaboration Development Program to Develop a treatment for LCA10.

1.38 "**Licensee**" means, with respect to a particular Editas Product, a Third Party to whom Editas has granted a license under any Know-How or Patents Controlled by Editas, but excluding any Third Party acting solely as a distributor.

1.39 "**Manufacture**" means all activities related to the manufacturing of a compound or product, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing.

1.40 "**Materials**" means all documentation, information, and biological, chemical and other materials exchanged between the Parties in connection with Services under the MSA.

1.41 "**Net Sales**" shall mean, with respect to an Editas Product in a country in the Territory, the gross amount invoiced for sale or other disposition of such Editas Product in such country by Editas, its Affiliates, Licensees, or Sublicensees to Third Parties (including distributors, wholesalers and end users), less the following deductions accounted for in accordance with GAAP:

(a) sales returns and allowance actually paid, granted or accrued on the Editas Product, including trade quantity, prompt pay and cash discounts and adjustments, granted on account of price adjustments or billing errors;

(b) credits or allowances given or made for rejection, recall, return, wastage, replacement of, and for uncollectible amounts on, Editas Products or for rebates or retroactive price reductions;

(c) price reductions, rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers (including Medicare, Medicaid, managed care and similar types of rebates and chargebacks);

(d) costs of outbound freight, insurance, and other transportation charges to the extent separately invoiced to the customer and included in gross amounts invoiced, as well as inventory management fees or similar fees for bona fide services provided by wholesalers, distributors, warehousing chains and other Third Parties related to the distribution of such Editas Product;

(e) taxes, duties or other governmental charges (including any tax such as a value added or similar tax, other than any taxes based on income) relating to the sale of such Editas Product, as adjusted for rebates and refunds, including pharmaceutical excise taxes;

(f) the portion of administrative fees paid during the relevant time period to group purchasing organizations or pharmaceutical benefit managers relating to such Editas Product;

(g) that portion of, as applicable, (i) the annual fee on prescription drug manufacturers imposed by the PPACA or (ii) the user fees imposed on device manufacturers by the Medical Device User Fee and Modernization Act of 2002, in each case that Editas or its Affiliates allocates to sales of the Editas Products in accordance with Editas' or its Affiliate's standard policies and procedures consistently applied across its products; and

(h) any other deductions not otherwise itemized above but which are hereinafter consistently applied across Editas' products as a result of a change in applicable Law or GAAP, provided that [**];

to the extent such deductions: (i) are applicable and in accordance with standard allocation procedures, (ii) have not already been deducted or excluded, (iii) are incurred in the ordinary course of business in type and amount consistent with good industry practice, and (iv) except with respect to the uncollectible amounts and pharmaceutical excise taxes described in subsections (b) and (e) above, are determined in accordance with GAAP. Net Sales shall not be imputed to

transfers of Editas Product without consideration or for nominal consideration for use in any clinical trial, or for any bona fide charitable, compassionate use or indigent patient program purpose or as a sample. For the avoidance of doubt, in the case of any transfer of any Editas Product between or among Editas and its Affiliates, Licensees, or Sublicensees for resale, Net Sales shall be determined based on the sale made by such Affiliate, Licensee, or Sublicensee to a Third Party. In the case of any sale for value, such as barter or counter-trade, of an Editas Product, or part thereof, other than in an arm's length transaction exclusively for cash, Net Sales shall be deemed to be the Net Sales at which substantially similar quantities of such Editas Product are sold for cash in an arm's length transaction in the relevant country.

Notwithstanding anything to contrary contained herein, the following shall not be considered Net Sales for purposes of this Agreement: sales of (A) an Editas Product by a Licensee or Sublicensee pursuant to a compulsory license (provided that, any actual monies received by Editas or its Affiliates pursuant to such compulsory license shall be treated as Net Sales) or (B) an Editas Product as to which Editas or its Affiliate, Licensee, or Sublicensee does not receive any consideration tied to sales of such Editas Product. If Editas appoints a distributor to sell an Editas Product, then only the consideration actually paid to Editas or its Affiliate by such distributor shall be included in the calculation of Net Sales.

1.42 "**Patent**" means (a) all patents and patent applications in any country or supranational jurisdiction in the Territory, (b) any substitutions, divisionals, continuations, continuations-in-part, provisional applications, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like of any such patents or patent applications, and (c) foreign counterparts of any of the foregoing.

1.43 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority, or any other entity not specifically listed herein.

1.44 "**Regulatory Approval**" means the approval, license or authorization of the applicable Regulatory Authority for the marketing and sale of a product for a particular indication in a country in the Territory.

1.45 "**Regulatory Authority**" means the FDA in the U.S. or any health regulatory authority in another country in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval in such country, including the EMA and any successor(s) thereto.

1.46 "**Regulatory-Based Exclusivity**" means with respect to an Editas Product in a country in the Territory, that (a) Editas or any its Affiliates, Licensees, or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of applicable Law) in such country to market and sell such Editas Product in such country, or (b) the data and information submitted by Editas or any of its Affiliates, Licensees, or Sublicensees to the relevant Regulatory Authority for purposes of obtaining Regulatory Approval for such Editas Product may not be disclosed, referenced, used or relied upon in any way by the relevant Regulatory Authority (including by relying upon the Regulatory

Authority's previous findings regarding the safety or effectiveness of such Editas Product) to support the Regulatory Approval or marketing of any product by a Third Party.

1.47 "**Regulatory Materials**" means any regulatory application, submission, notification, communication, correspondence, registration and other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, Manufacture, or Commercialize any Editas Product in any Field in a particular country or jurisdiction.

1.48 "**Services**" means the services performed by Allergan for Editas under the MSA.

1.49 "**Sublicensee**" means, with respect to a particular Editas Product, a Third Party to whom Editas has granted a sublicense under any Know-How licensed to Editas pursuant to this Agreement, but excluding any Third Party acting solely as a distributor or manufacturer.

1.50 "**Territory**" means the entire world.

1.51 "**Third Party**" means any Person other than Editas or Allergan that is not an Affiliate of Editas or of Allergan.

1.52 "**United States**" or "**U.S.**" means the United States of America and all of its territories and possessions.

1.53 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of the Agreement:

Defined Terms	**Section**
Agreement	Preamble
Allergan	Preamble
Allergan Indemnitee	7.1
APIL	Recitals
Applicable Agreement	2.6(a)
Arbitration Request	8.6(b)
Collaboration Agreement	Recitals
Disclosing Party	4.1(a)
Editas	Preamble
Editas Indemnitee	7.2
Effective Date	Preamble
Indemnified Party	7.3
Indemnifying Party	7.3
Intercompany License	Recitals
Inventory	2.5
Know-How Transfer	2.3
LCA10 Products	Recitals
MSA	Recitals

Defined Terms	Section
Option	Recitals
Party	Preamble
Profit-Sharing Agreement	Recitals
Receiving Party	4.1(a)
Royalty Term	3.6(a)
Settlement Payments	2.1(d)
Transferred Regulatory Filings	2.4
TSA	Recitals
VAT	3.12(b)
Withholding Taxes	3.12(a)

1.54 Interpretation. In this Agreement, unless otherwise specified:

(a) The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation";

(b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(c) the word "or" is used in the inclusive sense typically associated with the phrase "and/or";

(d) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear;

(e) "days" means calendar days; and

(f) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

ARTICLE 2
Termination and Reversion of Editas Products

2.1 Termination.

(a) Collaboration Agreement. The Parties hereby terminate the Collaboration Agreement and rights and obligations of the Parties thereunder. Without limiting the generality of the foregoing, the Parties acknowledge and agree that, upon the Effective Date, (i) all Options (as defined in the Collaboration Agreement) that are unexercised as of the Effective Date shall terminate and be of no force or effect, and (ii) Allergan shall have no further obligations to make any milestone, royalty or other payments to Editas under Article 6 of the Collaboration Agreement.

(b) Profit-Sharing Agreement. Pursuant to Section 10.7 of the Profit-Sharing Agreement, the Parties hereby acknowledge and agree that the Profit-Sharing Agreement will

terminate upon termination of the Collaboration Agreement. The Parties shall cease to share the Development Costs, Royalty & Milestone Payments and Profit and Losses (as each term is defined in the Profit-Sharing Agreement) with respect to the LCA10 Products as of the Effective Date.

(c) MSA. Pursuant to Section 10.1 of the MSA, the Parties hereby acknowledge that the MSA will terminate upon termination of the Collaboration Agreement, and neither Allergan nor Editas will have any further obligations under the MSA, except that (i) Allergan shall terminate all Services in progress in an orderly manner as soon as practical, and (ii) Allergan shall deliver to Editas or, at Editas' option, dispose of, any Materials in its possession or control and all Deliverables developed through expiration, at Editas' expense.

(d) Settlement of Final Balances. **Exhibit A** sets forth any amounts owing by either Party to the other Party pursuant to each of the Collaboration Agreement, the Profit-Sharing Agreement, and the MSA to the extent known by either Party as of the Effective Date (the "**Settlement Payments**"). The Settlement Payments shall be made no later than [**] following the Effective Date, provided, that any Settlement Payment owed by either Party may be offset by the amount of any Settlement Payment owed to such Party, provided, further, that any Settlement Payments owed by Allergan to Editas may be deducted from the amount of the payment under Section 3.2(a). If, during the [**] period following the Effective Date, either Party determines that the Settlement Payments did not accurately reflect the amounts actually owed by either Party to the other Party under the Collaboration Agreement, Profit-Sharing Agreement or MSA as of the Effective Date, such Party shall promptly notify the other Party, and the Parties shall cooperate in good faith to calculate any appropriate adjustments to the amount of the Settlement Payments. Each Party, as applicable, shall pay to the other Party the amount of any adjustments to the Settlement Payments within [**] of the Effective Date.

2.2 Intellectual Property Rights.

(a) Allergan hereby grants Editas a non-exclusive, royalty-bearing right and license, including the right to grant sublicenses (through multiple tiers), to the Allergan Know-How that is necessary to Develop, Manufacture and Commercialize the Existing Compound in any Field in the Territory.

(b) The Parties acknowledge and agree that, as a result of the termination of the Collaboration Agreement, all licenses and other rights granted to Allergan pursuant to Section 4.2 of the Collaboration Agreement shall be terminated and of no further force and effect.

2.3 Know-How Transfer. Allergan shall (a) transfer and deliver (including when available, in electronic format) the Allergan Know-How set forth on **Exhibit B**, to the extent such Allergan Know-How is in the Control of Allergan, its Affiliates or its sublicensees as of the Effective Date, to Editas or its designee, through the delivery of documents to a data room or other means to be agreed between the Parties (the "**Know-How Transfer**"), and (b) provide Editas or its designee reasonable technical assistance in connection with the Allergan Know-How related to Manufacturing the Editas Products, which shall be conducted on site at Allergan or by teleconference, unless the Parties otherwise agree. The Parties shall use Commercially Reasonable Efforts to complete the activities contemplated by this Section 2.3 within [**] after the Effective Date.

2.4 Regulatory Materials and Assistance. Within [**] of the Effective Date, Allergan shall transfer, assign and deliver to Editas all (a) existing regulatory filings, (b) regulatory submission Materials relating to any Editas Product, (c) data from any preclinical and clinical studies conducted by or on behalf of Allergan, its Affiliates or its sublicensees relating to any Editas Product, and (d) pharmacovigilance data (including all adverse event databases) in the Control of Allergan or its Affiliates or sublicensees solely relating to any Editas Product (clauses (a) and (b), collectively, the "**Transferred Regulatory Filings**"), in each case all as set forth on **Exhibit C**. Such transfer shall be effectuated through submission of filing ownership transfer and the delivery of documents to a data room or other means to be agreed between the Parties.

2.5 Inventory Transfer. Promptly after the Effective Date, Allergan shall transfer to Editas or its designee all inventories of the Existing Compound (the "**Inventory**") as set forth in **Exhibit D**, provided that Allergan shall have no obligation to transfer, and Editas shall have no obligation to pay for, any Inventory that is identified on **Exhibit D** as being in the possession of any Third Party as of the Effective Date until all necessary approvals from such Third Party to transfer such Inventory to Editas are received. An estimated cost for the Inventory is set forth in **Exhibit D**. All deliveries of Inventory shall be made to Editas or its designee on FCA (Incoterms 2020) basis at the location set forth for the applicable Inventory on **Exhibit D**. Notwithstanding anything to the contrary in this Agreement, the title of the Inventory set forth on **Exhibit D** or otherwise delivered in accordance with this Section 2.5 shall be transferred from Allergan to Editas as of the date when such Inventory is delivered to Editas or its designee in accordance with this Section 2.5. In consideration of the transfer of the Inventory (other than to the extent Editas has already compensated Allergan for such Inventory pursuant to the Collaboration Agreement), Editas shall pay to Allergan an amount equal to (a) [**] percent ([**]%) of the actual cost of Inventory related to the Existing Compound and identified as such on **Exhibit D** and (b) [**] percent of the cost of the [**] inventory identified as such on **Exhibit D**, in each case within [**] of receipt of an invoice therefor.

2.6 Contract Assignments and Sublicenses.

(a) Upon request by Editas, Allergan shall promptly provide a copy of each agreement listed in **Exhibit E** (each, an "**Applicable Agreement**") to Editas, subject to the consent (if required) of the counterparty thereto and reasonably redacted to the extent unrelated to the Existing Compound. Editas may request that Allergan assign or sublicense the rights and have Editas assume the obligations under any Applicable Agreement. Upon such request from Editas for assignment or sublicense of an Applicable Agreement, Allergan shall (i) use its Commercially Reasonable Efforts to assign or sublicense to Editas its rights under such Applicable Agreement, to the extent related to the Existing Compound, subject to Editas assuming the then-remaining unaccrued obligations under such Applicable Agreement (including the payment of any royalties or other amounts accrued for activities occurring after the Effective Date) to the extent related to the Existing Compound, and (ii) permit Editas access to any communication portal (if any) established with the counterparty of such Applicable Agreement, subject to consent (if required) of the counterparty of such Applicable Agreement.

(b) Allergan shall not to be obligated to propose, discuss, or negotiate any amendment to the terms and conditions of any Applicable Agreement before assignment or sublicense to Editas. Allergan does not represent or warrant that a counterparty of any Applicable

Agreement whose consent is necessary to effectuate the relevant assignment or sublicense will agree to assign or sublicense such Applicable Agreement to Editas.

2.7 Transition Efforts. Without limiting Sections 2.3 through 2.6, the Parties shall use its Commercially Reasonable Efforts to ensure an orderly Know-How Transfer and transfer of the Transferred Regulatory Filings.

2.8 Transition Costs. Allergan shall provide a maximum of [**] total man-hours in connection with its activities pursuant to Sections 2.3 through 2.6 and the TSA unless otherwise agreed by the Parties. All man-hours in connection with such activities in excess of [**] total man-hours will be billed by Allergan to Editas at the FTE Rate. Except as otherwise specified in this Section 2.8, Allergan shall be responsible for its internal costs and Editas shall be responsible for all out-of-pocket expenses of Allergan payable to Third Parties in connection with activities pursuant to Sections 2.3 through 2.6.

2.9 Relationship to Other Agreements. Notwithstanding anything to the contrary in the Collaboration Agreement, the Profit-Sharing Agreement or the MSA (including the survival provisions therein), except as otherwise set forth in this Agreement, after the Effective Date, (a) the rights and obligations of the Parties under the Collaboration Agreement, the Profit-Sharing Agreement and the MSA are terminated in their entirety (notwithstanding any survival provisions therein to the contrary), and (b) as between the Parties, the rights and obligations of the Parties with respect to any Editas Product shall be subject exclusively and solely to the terms and conditions of this Agreement. Specifically and without limiting the foregoing, neither Party shall have any payment obligation to the other Party in connection with any Editas Product (in the form of payment, offset, credit or otherwise), other than as specifically set forth in this Agreement.

ARTICLE 3
Financial and Operational Obligations

3.1 Editas Obligations.

(a) From and after the Effective Date, Editas shall bear all costs of Development, regulatory activities, Manufacturing and Commercialization for the Editas Products in the Territory. Editas shall use Commercially Reasonable Efforts to Develop and Commercialize an Editas Product directed to each Collaboration Program Target. During the term of this Agreement, Editas shall provide to Allergan reports no less frequently than [**], which shall set forth in reasonable detail Editas' Development and Commercialization plans and activities, including timelines.

(b) Within [**] of the Effective Date, Editas shall select for Development [**] and provide written notice to Allergan of such selection.

3.2 Payments. In partial consideration for Editas' reimbursement of expenses to Allergan and in partial consideration of the rights granted and obligations undertaken by Allergan pursuant to this Agreement, Editas shall pay Allergan (a) a one-time, non-refundable, non-creditable payment of US$17,500,000 within [**] of the Effective Date, and (b) an additional one-

time, non-refundable, non-creditable payment of US$2,500,000 within [**] after completion of the transition services in Exhibit A of the TSA, provided that such payment shall be made no later than [**] after the Effective Date so long as Allergan is not then in material breach of its obligations under Section 2.3, and in such case in which Allergan is in material breach, such payment shall be made when the transition services in Exhibit A of the TSA have been completed.

3.3 Development Milestones. In partial consideration for the rights and licenses granted to Editas hereunder, Editas shall make the following non-refundable, non-creditable milestone payments to Allergan, on a Collaboration Program Target-by-Collaboration Program Target basis, for the first Editas Product directed to such Collaboration Program Target that achieves such milestone, within [**] after the first achievement by Editas or its Affiliates, Licensees or Sublicensees of the regulatory events set forth in the table below. For clarity, each milestone payment below shall be payable only once per Collaboration Program Target, regardless of how many Editas Products directed toward such Collaboration Program Target achieve the applicable milestone.

Development Milestone	**Milestone Payment**
[**]	US$[**]
[**]	US$[**]

3.4 Commercialization Milestones. In partial consideration for the rights and licenses granted to Editas hereunder, Editas shall make the following non-refundable, non-creditable milestone payments to Allergan, on a Collaboration Program Target-by-Collaboration Program Target basis for the first Editas Product directed to such Collaboration Program Target that achieves such milestone, within [**] after the first achievement by Editas or its Affiliates, Licensees or Sublicensees of the commercialization events set forth in the table below. For clarity, each milestone payment below shall be payable only once per Collaboration Program Target, regardless of how many Editas Products directed toward such Collaboration Program Target achieve the applicable milestone.

Commercialization Milestone	**Milestone Payment**
[**]	US$[**]
[**]	US$[**]

3.5 Sales-Based Milestones. In partial consideration for the rights and licenses granted to Editas hereunder, Editas shall make the following non-refundable, non-creditable milestone payments to Allergan within [**] after the first achievement by Editas or its Affiliates, Licensees or Sublicensees of the sales-based events set forth in the table below. For clarity, each milestone payment below shall be payable only once.

Sales-Based Milestone	Milestone Payment
Annual Net Sales of all Editas Products in all Editas Programs exceed US$[**]	US$[**]
Annual Net Sales of all Editas Products in all Editas Programs exceed US$[**]	US$[**]
Annual Net Sales of all Editas Products in all Editas Programs exceed US$[**]	US$[**]

3.6 Royalties and Adjustments.

(a) In partial consideration for the rights and licenses granted to Editas hereunder, Editas shall pay Allergan royalties equal to [**]% of Net Sales of Editas Products in the Territory. Payments due from Editas to Allergan under this Section 3.6 shall be paid within [**] after the end of each Calendar Quarter. Editas' royalty obligations to Allergan under this Section 3.6 shall commence on a country-by-country and Editas Product-by-Editas Product basis on date of the First Commercial Sale by Editas or its Affiliates, Licensees, or Sublicensees of the relevant Editas Product in the relevant country and shall expire on a country-by-country basis and Editas Product-by-Editas Product basis on the later of the following, as applicable: (i) the expiration of Regulatory-Based Exclusivity with respect to such Editas Product in such country, and (ii) the tenth (10^{th}) anniversary of the First Commercial Sale of such Editas Product (the "**Royalty Term**").

(b) If, on an Editas Product-by-Editas Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, if one or more Biosimilar Products is commercially available in such country and such Biosimilar Products have a market share of [**] percent ([**]%) or more of the aggregate market in such country of such Editas Product and the Biosimilar Products during such Calendar Quarter (based on sales of units of such Editas Product and such Biosimilar Products, as reported by IMS International, or if such data are not available, such other reliable data source as reasonably determined by the Parties), then the royalties otherwise payable pursuant to Section 3.6(a) with respect to such Editas Product in such market during such Calendar Quarter shall be reduced to [**]%.

3.7 Reports. Until the expiration of Editas' royalty and other payment obligations under this Article 3, Editas shall make written unaudited reports to Allergan within [**] after the end of each Calendar Quarter covering sales of Editas Products on an Editas Product-by-Editas Product and country-by-country basis in the Territory by Editas and its Affiliates, Licensees, and Sublicensees during such Calendar Quarter. Each such written report shall provide (a) the Net Sales in Dollars and local currency for each Editas Product in the Territory during the reporting period and (b) the royalties payable, in Dollars, which shall have accrued hereunder with respect to such Net Sales. The information contained in each report under this Section 3.7 shall be considered Confidential Information of Editas. Concurrent with the delivery of each such report,

Editas shall make the royalty payment due to Allergan for the Calendar Quarter covered by such report.

3.8 Methods of Payments. All payments due from one Party to the other Party under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the payee Party.

3.9 No Other Payments. Except as expressly set forth in this Agreement, neither Party shall have any payment obligation to the other Party with respect to any Editas Products.

3.10 Currency. All amounts payable and calculations hereunder shall be in Dollars. When conversion of payments from any foreign currency is required to be undertaken by a Party, the Dollar equivalent shall be calculated using such Party's then-current standard exchange rate methodology as applied in its external reporting.

3.11 Late Payments. Any undisputed amount owed by one Party to the other Party under this Agreement that is not paid on or before the date such payment is due shall bear interest at a rate per annum equal to the lesser of the prime or equivalent rate per annum quoted by *The Wall Street Journal* on the first Business Day after such payment is due, plus [**] percent ([**]%), or the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after such payments are due and compounded monthly. Interest shall not accrue on undisputed amounts that were paid after the due date as a result of mistaken payee Party actions (*e.g.*, if a payment is late as a result of the payee Party providing an incorrect account for receipt of payment). In addition, the payor Party shall reimburse the payee Party for all costs, including attorneys' fees and legal expenses, incurred in the collection of late payments; provided that the foregoing shall not apply to payments disputed in good faith by the payor Party unless the payee Party is successful in such dispute or the payor Party ceases to dispute such payments.

3.12 Taxes.

(a) Withholding Taxes. The Parties shall reasonably cooperate with one another to avoid or reduce tax withholding or similar obligations in respect of any payments made by a Party to the other Party under this Agreement. To the extent such paying Party is required by applicable Law to deduct and withhold taxes on any payment to the other Party ("**Withholding Taxes**"), then the paying Party shall pay such Withholding Taxes to the applicable Governmental Authority and make the payment to the receiving Party of the net amount due after deduction or withholding of such taxes, and such Withholding Taxes shall be treated for all purposes of this Agreement as having been paid to the receiving Party hereunder. The paying Party shall submit proof of payment along with reasonable supporting documentation and calculations of such Withholding Taxes sufficient to enable the other Party to claim such payment of Withholding Taxes or otherwise obtain any tax benefit for such Withholding Taxes within a reasonable period of time after such Withholding Taxes are remitted to the Governmental Authority; provided that if any change in control, change in tax residence, sublicense or assignment of this Agreement by law or otherwise by the paying Party, or any similar action, would change the payor's jurisdiction of incorporation or residence for tax purposes and result in Withholding Taxes that did not exist prior to such action, then the amount of any payment by such paying Party shall be increased so that the net amount payable to the receiving Party after such incremental Withholding Taxes

incurred as a result of such action equals the amount of the payment that would otherwise have been payable but for such action; provided, further that Editas shall not withhold any Withholding Taxes from the upfront payments provided for in Section 3.2. Prior to making any deduction or withholding from any payment under this Agreement, the paying Party shall provide at least [**] prior written notice to the other Party of the amounts subject to deduction or withholding and the legal basis therefor, and provide to the other Party a reasonable opportunity to furnish forms, certificates or other items that would reduce or eliminate such deduction or withholding. Each Party shall provide the other Party with reasonable assistance (i) to enable the recovery, as permitted by Law, of Withholding Taxes or similar obligations resulting from payments made under this Agreement and (ii) in connection with any audit by any tax authority relating to this Agreement. If the paying Party receives a refund of any such withheld Withholding Taxes, in whole or in part, and whether in the form of cash, credit or other similar offset, the paying Party shall refund such amount to the other Party within a reasonable period of time, provided the paying Party shall not be obligated to pay any amount in excess of the gross payment due to the receiving Party. The receiving Party shall not be liable for any penalties or interest due to the failure of the paying Party to properly withhold or remit any such Withholding Tax to the Governmental Authorities, unless such failure is due to incorrect or invalid forms, facts, or other applicable information given to the paying Party by the other Party.

(b) VAT. Notwithstanding anything contained in Section 3.12(a), this Section 3.12(b) shall apply with respect to any value added tax, ad valorem, sales and use, goods and services or similar tax chargeable on the supply or deemed supply of goods or services, sales and use taxes, transaction taxes, consumption taxes and other similar taxes required by applicable Law, including any interest, penalties or other additions to tax thereon, required under applicable Law (collectively, "**VAT**"). All payments are exclusive of VAT. If any VAT is chargeable in respect of any such payment under applicable Law, the paying Party shall pay VAT at the applicable rate in respect of such payment as follows: (i) where the liability to collect, account for, or remit such VAT is a liability of the receiving Party, following the receipt of a valid VAT invoice in the appropriate form issued by the receiving Party in respect of such payment, such VAT to be payable on the later of the due date of the payment to which such VAT relates and [**] after the receipt by the paying Party of the applicable valid invoice relating to that VAT payment (provided, however, that the receiving Party shall return such VAT within a reasonable period of time to the extent that the receiving Party actually receives under applicable Law a refund or recovery of such VAT) or (ii) where the liability to collect, account for, or remit such VAT is a liability of the paying Party, timely account and pay for all applicable VAT to the proper tax authority. If the liability to collect, account for, or remit such VAT is a liability of the receiving Party, the paying Party shall not be responsible for any penalties, interest, and other additions thereon resulting from the failure by the receiving Party to collect (if not included on a valid VAT invoice) or remit any such VAT. The Parties shall reasonably cooperate to eliminate or minimize the amount of any such VAT imposed on the transactions contemplated in this Agreement.

3.13 Records and Audit Rights. Editas shall maintain complete and accurate records in sufficient detail to permit Allergan to confirm the accuracy of the amount of the royalty payments and other amounts payable under this Agreement. Upon not less than [**] prior notice, such records shall be open during regular business hours for a period of [**] from the creation of individual records for examination by an independent certified public accountant selected by Allergan and reasonably acceptable to Editas for the sole purpose of verifying for Allergan the

accuracy of the financial reports furnished by Editas pursuant to this Agreement or of any payments made, or required to be made, by or to Editas pursuant to this Agreement. Such audits shall not occur more often than [**], and shall be conducted under appropriate confidentiality provisions. Such auditor shall not disclose Editas' Confidential Information to Allergan, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Editas or the amount of payments under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [**] after the accountant's report, plus interest, from the original due date. Allergan shall bear the full costs of such audit unless such audit reveals an underpayment by Editas that resulted from a discrepancy in the financial report provided by Editas for the audited period, which underpayment was more than [**] percent ([**]%) of the amount set forth in such report, in which case Editas shall reimburse Allergan for the costs for such audit.

ARTICLE 4
Confidentiality

4.1 Duty of Confidence. Subject to the other provisions of this Article 4:

(a) All Confidential Information of a Party (the "**Disclosing Party**") shall be maintained in confidence and otherwise safeguarded by the other Party (the "**Receiving Party**") and its Affiliates, using diligent efforts, but in any event no less than in the same manner and with the same protections as the Receiving Party maintains its own confidential information;

(b) The Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement; and

(c) The Receiving Party may disclose such Confidential Information to (i) its Affiliates, Licensees, and Sublicensees, and (ii) the officers, employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates, Licensees, and Sublicensees, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such Persons are bound by legally enforceable obligations to maintain the confidentiality of the Confidential Information in a manner consistent with the confidentiality provisions of this Agreement.

4.2 Exceptions. The obligations set forth in Section 4.1 as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate through competent evidence that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt without an obligation of confidentiality, and not through a prior disclosure by the Disclosing Party, as documented by the Receiving Party's business records;

(b) is in the public domain before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of the Receiving Party;

(c) is subsequently disclosed to the Receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures shall be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party, unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

4.3 Authorized Disclosures. Notwithstanding the obligations set forth in Sections 4.1 and 4.4, a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent:

(a) such disclosure: (i) is reasonably necessary for the filing or prosecuting Patents; (ii) is reasonably necessary in connection with regulatory filings for any Editas Product; (iii) is reasonably necessary for prosecuting or defending litigation; or (iv) is made to any Third Party bound by written obligations of confidentiality and non-use substantially consistent with those set forth in this Article 4, to the extent otherwise necessary or appropriate in connection with the exercise of its rights or the performance of its obligations hereunder;

(b) such disclosure is reasonably necessary: (i) to such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to such Party, provided that in each such case on the condition that such directors, attorneys, independent accountants and financial advisors are bound by obligations of confidentiality and non-use substantially consistent with those set forth in this Article 4; or (ii) to actual or potential investors, acquirors, (sub)Licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration; provided that in each such case on the condition that such Persons are bound by written obligations of confidentiality and non-use substantially consistent with those set forth in this Article 4; or

(c) such disclosure is required by judicial or administrative process, provided that in such event such Party shall promptly notify the other Party in writing of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article 4, and the Party disclosing Confidential Information pursuant to Law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

4.4 Publicity; Use of Names.

(a) The Parties, either jointly or separately, will issue a press release after the execution of this Agreement in a form attached as **Exhibit F** at such time as mutually agreed by the Parties. No other disclosure of the existence or the terms, including financial terms, of this Agreement may be made by either Party or its Affiliates except as provided in Section 4.3 and this Section 4.4. No Party shall use the name, trademark, trade name or logo of the other Party, its

Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, except as provided in this Section 4.4 or with the prior express written permission of the other Party, except as may be required by applicable Law. Notwithstanding the foregoing, Editas, its Sublicensees and its and their respective Affiliates shall have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Editas Products; provided that (i) such disclosure is subject to the provisions of Article 4 with respect to Allergan's Confidential Information and (ii) Editas shall not refer to this Agreement or use the name of Allergan or its Affiliates (or insignia, or any contraction, abbreviation or adaptation thereof) in such disclosure without Allegan's prior written permission.

(b) A Party may disclose this Agreement in securities filings with the Securities Exchange Commission or equivalent foreign agency to the extent required by applicable Law. In such event, the Party seeking such disclosure shall prepare a proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party shall promptly (and in any event, no less than [**] after receipt of such proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines prescribed by applicable Law. The Party seeking such disclosure shall reasonably consider any comments thereto provided by the other Party within such [**] period.

(c) Each Party acknowledges that the other Party may be legally required to make public disclosures (including in filings with Governmental Authorities or by issuing a press release) of certain terms of or material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by Law, provided that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, and shall reasonably consider any comments thereto provided by the other Party within [**] after the receipt of such proposed disclosure, provided that in no event shall the Party having such disclosure obligation be required to delay its disclosure in a manner that may cause such Party to violate any Law or incur any legal liability.

(d) Except for any press release or other public disclosures issued pursuant to Section 4.4(a), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder, whether made jointly or separately, that would disclose information other than that already in the public domain, shall first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld or delayed). The Parties shall use reasonable efforts to coordinate the timing of such disclosures to be outside the trading hours of the NASDAQ or NYSE stock markets, provided that neither Party shall be required to so delay such a disclosure where such delay would reasonably be expected to give rise to liability for or sanctions upon such Party in such Party's sole judgment.

(e) The Parties agree that after a disclosure or other public announcement is made pursuant to this Section 4.4, either Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent or approval.

(f) Each Party agrees that the other Party shall have the right to use such first Party's name and logo in presentations, the company's website, collateral materials and corporate

overviews to describe the relationship between the Parties under this Agreement, as well as in taglines of press releases issued pursuant to this Section 4.4.

ARTICLE 5
Term

5.1 Term. The term of this Agreement shall commence upon the Effective Date and shall continue until the expiration of the applicable Royalty Term on an Editas Product-by-Editas Product and country-by-country basis.

5.2 Effect of Expiration. After the expiration of this Agreement pursuant to Section 5.1, Editas' rights and licenses with respect to such Editas Product in such country shall survive as fully-paid up, non-royalty bearing, rights and licenses.

ARTICLE 6
Representations and Warranties

6.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation or formation and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder; and

(c) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material applicable Law.

6.2 Additional Representations and Warranties by Allergan. Allergan represents and warrants to Editas as of the Effective Date that:

(a) there are no issued or pending Allergan Patents;

(b) it has the right to grant the licenses to Editas as purported to be granted under Section 2.2, and it has not granted any license, right or interest in, to or under any Allergan Know-How to any Third Party that is inconsistent with the licenses granted to Editas under Section 2.2; and

(c) upon delivery to a carrier selected by Editas on the agreed date of delivery in accordance with the terms and conditions of Section 2.5, the Inventory shall (i) meet the applicable specifications for such Inventory, and (ii) to the extent Inventory has been manufactured

according to Good Manufacturing Practice, have been manufactured in accordance with current Good Manufacturing Practices.

6.3 No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 6, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF ALLERGAN OR EDITAS, AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE HEREBY EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

6.4 Sole Remedy. Notwithstanding anything to the contrary contained in this Agreement, Editas' sole remedy for breach of any of the representations and warranties contained in Section 6.2(c) shall be for Allergan to pay Editas in cash an amount equal to Allergan's manufacturing cost for such defective Inventory, which the Parties agree shall be the amount for the applicable category of Inventory set forth on **Exhibit D**.

ARTICLE 7
Indemnification; Limitations of Liability

7.1 Indemnification by Editas. Editas shall indemnify and hold Allergan and its Affiliates, Licensees, and Sublicensees and its and their respective officers, directors, agents and employees (the "**Allergan Indemnitees**") harmless from and against any Claims against them to the extent arising or resulting from:

(a) the negligence, recklessness or wrongful intentional acts or omissions of Editas or its Affiliates and its or their respective directors, officers, employees and agents, in connection with (i) Editas' performance of its obligations or exercise of its rights under this Agreement or (ii) Editas' performance of its obligations or exercise of its rights prior to the Effective Date under the Collaboration Agreement, the Profit-Sharing Agreement or the MSA;

(b) failure by Editas to comply with any Law;

(c) any breach of any representation or warranty or express covenant made by Editas under this Agreement; or

(d) the Development, Manufacture or Commercialization by Editas or its Affiliates, Licensees or Sublicensees of any Editas Product;

in each case, except to the extent any such Claims (i) result from the negligence or willful misconduct of an Allergan Indemnitee, (ii) arise from the breach of any representation or warranty or obligation under this Agreement, the Collaboration Agreement, the Profit-Sharing Agreement or the MSA by Allergan or (iii) are subject to indemnification by Allergan under Section 7.2.

7.2 Indemnification by Allergan. Allergan shall indemnify and hold Editas and its Affiliates, Licensees, and Sublicensees and its and their respective officers, directors, agents and

employees (the "**Editas Indemnitees**") harmless from and against any Claims arising under or related to this Agreement against them to the extent arising or resulting from:

(a) the negligence, recklessness or wrongful intentional acts or omissions of Allergan or its Affiliates and its or their respective directors, officers, employees and agents, in connection with (i) Allergan's performance of its obligations or exercise of its rights under this Agreement or (ii) Allergan's performance of its obligations or exercise of its rights prior to the Effective Date under the Collaboration Agreement, the Profit-Sharing Agreement or the MSA;

(b) any breach of any representation or warranty or express covenant made by Allergan under this Agreement;

(c) failure by Allergan to comply with any Law; or

(d) the Development, Manufacture, or Commercialization by Allergan or its Affiliates, Licensees, or Sublicensees (excluding Editas) of the Existing Compound prior to the Effective Date;

except, in each case, to the extent any such Claims (i) result from the negligence or willful misconduct of an Editas Indemnitee, (ii) arise from the breach of any representation or warranty or obligation under this Agreement, the Collaboration Agreement, the Profit-Sharing Agreement or the MSA by Editas or (iii) are subject to indemnification by Editas under Section 7.1.

7.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 7.1 or 7.2 (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the Claim giving rise to the obligation to indemnify as soon as reasonably practicable after receiving notice of the Claim. The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 7.1 or 7.2 as to any Claim, pending resolution of the dispute pursuant to Section 8.6, the Parties may conduct separate defenses of such Claim, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 7.1 or 7.2 upon resolution of the underlying Claim.

7.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this Article 7. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

7.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR

INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 7.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER SECTIONS 6.4, 7.1 OR 7.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ARTICLE 4.

7.6 Insurance. Editas shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Editas Product is being clinically tested in human subjects or commercially distributed or sold. Editas shall provide Allergan with evidence of such insurance upon request and shall provide Allergan with written notice at least [**] prior to the cancellation or non-renewal of, or material changes in, such insurance. Such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 7.

ARTICLE 8
General Provisions

8.1 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, earthquakes or other acts of God, epidemics or pandemics (including any government or private action in reaction thereto), or acts, generally applicable action or inaction by any Governmental Authority (but excluding any government action or inaction that is specific to such Party, its Affiliates or its Sublicensees, such as revocation or non-renewal of such Party's license to conduct business), or omissions or delays in acting by the other Party, or unavailability of materials related to the Manufacture of any Editas Products. The affected Party shall notify the other Party in writing of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

8.2 Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party, or in whole to its successor-in-interest in connection with the sale of all or substantially all of its stock or its assets to which this Agreement relates, or in connection with a merger, acquisition or similar transaction. Any attempted assignment not in accordance with this Section 8.2 shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms

and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

8.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision with a valid, legal and enforceable provision which, insofar as practical, implements the purposes of this Agreement.

8.4 Notices. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Editas:

Editas, Inc.
11 Hurley Street
Cambridge, MA 02141
Attn: Chief Executive Officer
Copy to: Chief Legal Officer
Facsimile: [**]

with a copy to (which shall not constitute notice):

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attention: Steven D. Barrett, Esq.
E-mail: Steven.Barrett@wilmerhale.com
Telephone: (617) 526-6000
Facsimile: (617) 526-5000

If to Allergan:

Allergan Sales, LLC
5 Giralda Farms
Madison, New Jersey 07940
Facsimile: [**]

with a copy to (which shall not constitute notice):

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064

Attention: Vice Chairman, External Affairs, Chief Legal Officer and Corporate Secretary
Facsimile: [**]

or to such other address for such Party as it shall have specified by like notice to the other Party, provided that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice or request was deposited with the U.S. Postal Service.

8.5 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York and the patent Laws of the United States without reference to any rules of conflict of Laws. The application of the United Nations Convention on the International Sale of Goods to this Agreement or the performance thereof is expressly excluded.

8.6 Dispute Resolution.

(a) The Parties shall use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties are unable to resolve a given dispute pursuant to this Section 8.6(a) within [**], either Party may have the given dispute settled by binding arbitration pursuant to Section 8.6(b).

(b) If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and a statement of the issues for resolution.

(c) Within [**] after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution in a statement of counter-issues.

(d) Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patents Covering the Manufacture, use, importation, offer for sale or sale of Editas Products shall be submitted to a court of competent jurisdiction in the country in which such Patents were granted or arose.

(e) Any arbitration pursuant to this Section 8.6 will be held in New York, New York, United States unless another location is mutually agreed by the Parties. The arbitration will be governed under the rules of the International Chamber of Commerce, to the exclusion of any inconsistent state Law. The Parties shall mutually agree on the rules to govern discovery and the rules of evidence for the arbitration within [**] after the Arbitration Request. If the Parties fail to timely agree to such rules, the United States Federal Rules of Civil Procedure will govern discovery and the United States Federal Rules of Evidence will govern evidence for the arbitration. The arbitration will be conducted by three (3) arbitrators, of which each Party shall appoint one, and the arbitrators so appointed will select the third and final arbitrator. The arbitrators shall have experience in pharmaceutical licensing disputes. The arbitrator may proceed to an award,

notwithstanding the failure of either Party to participate in the proceedings. The arbitrator shall, within [**] after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrator shall be limited in the scope of his or her authority to resolving only the specific matter which the Parties have referred to arbitration for resolution and shall not have authority to render any decision or award on any other issues. Subject to Section 7.5, the arbitrator shall be authorized to award compensatory damages, but shall not be authorized to award punitive, special, consequential, or any other similar form of damages, or to reform, modify, or materially change this Agreement. The arbitrator also shall be authorized to grant any temporary, preliminary or permanent equitable remedy or relief the arbitrator deems just and equitable and within the scope of this Agreement, including an injunction or order for specific performance. The award of the arbitrator shall be the sole and exclusive remedy of the Parties, except for those remedies that are set forth in this Agreement or which apply to a Party by operation of the applicable provisions of this Agreement, and the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrator, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrator. Judgment on the award rendered by the arbitrator may be enforced in any court having competent jurisdiction thereof, subject only to revocation of the award on grounds set forth in the United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards.

(f) Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrator; provided, however, that the arbitrator, in his or her award, shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, transcripts, photocopy charges and travel expenses).

(g) Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the award of the arbitrator on the ultimate merits of any dispute.

(h) All proceedings and decisions of the arbitrator shall be deemed Confidential Information of each of the Parties.

8.7 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto and the TSA, contains the entire understanding of the Parties with respect to the subject hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments (including the Collaboration Agreement, the Profit-Sharing Agreement and the MSA), either oral or written, in respect to the subject hereof are superseded by the terms of this Agreement. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties.

8.8 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

8.9 Independent Contractors. Editas and Allergan are independent contractors and the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Editas nor Allergan shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

8.10 Waiver. The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

8.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law.

8.12 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, no ambiguity in this Agreement shall be strictly construed against either Party.

8.13 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

8.14 Further Actions. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as necessary or appropriate in order to carry out the purposes and intent of this Agreement.

8.15 Counterparts. This Agreement may be executed in two or more counterparts by original signature, facsimile or PDF files, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

EDITAS MEDICINE, INC.	**ALLERGAN SALES, LLC**
By: /s/ Cynthia Collins	By: /s/ Judith Tomkins
Name: Cynthia Collins	Name: Judith Tomkins
Title: CEO	Title: Assistant Secretary

[Signature Page to Termination Agreement]

Exhibits

Exhibit A – Settlement Payments

Exhibit B – Allergan Know-How

Exhibit C – Transferred Regulatory Filings, Materials and Data

Exhibit D – Inventory

Exhibit E – Applicable Agreements

Exhibit F – Press Release

Exhibit 31.1

CERTIFICATIONS

I, Cynthia Collins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Editas Medicine, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

By: /s/ Cynthia Collins
Cynthia Collins
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Michelle Robertson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Editas Medicine, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer
(Principal Financial 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 Editas Medicine, Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers 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 her or 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.

Date: November 6, 2020

By: /s/ Cynthia Collins
Cynthia Collins
Chief Executive Officer

Date: November 6, 2020

By: /s/ Michelle Robertson
Michelle Robertson
Chief Financial Officer