ELEVEN BIOTHERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

Filed 08/12/16 for the Period Ending 06/30/16

Address	215 FIRST STREET SUITE 400 CAMBRIDGE, MA 02142
Telephone	617-871-9911
CIK	0001485003
Symbol	EBIO
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

Table of Contents

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 June 30, 2016

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 No. 001-36296

Eleven Biotherapeutics, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	**26-2025616**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
215 First Street, Suite 400 Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (617) 871-9911

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

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

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

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

Number of outstanding shares of Common Stock as of July 31, 2016 : 20,058,298

ELEVEN BIOTHERAPEUTICS, INC.
TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future product research or development, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "goals," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the potential effectiveness of the License Agreement that we entered into with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. on June 10, 2016, and the impact of the transactions contemplated by the License Agreement, if it becomes effective;
- the outcome of our process to review a range of strategic alternatives with a goal of maximizing stockholder value;
- our plans to research and develop our product candidates;
- the initiation and conduct of clinical trials;
- our ability to successfully develop our product candidates and complete clinical programs;
- results of preclinical studies or other early stage studies and whether they will be indicative of the results of future studies;
- expectations regarding regulatory approvals, the nature and timing of our future interactions with regulatory authorities and our ability to design, implement and complete registration trials acceptable to such regulatory authorities and sufficient to support applications for regulatory approvals;
- the timing of and our ability to obtain marketing approval of our product candidates, and the ability of our product candidates to meet existing or future regulatory standards;
- the potential advantages of our product candidates;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates;
- our ability to enter into and successfully complete other collaborations or in-license or acquire rights to other products, product candidates or technologies;
- our ability to obtain, maintain and protect our intellectual property for our technology and products;
- the rate and degree of market acceptance and clinical utility of our products;
- our estimates regarding expenses, future revenues, capital requirements and need for additional financing;
- the impact of governmental laws and regulations; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and our stockholders 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 "Risk Factors" section, 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 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

ELEVEN BIOTHRAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share data)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 8,484	$ 36,079
Prepaid expenses and other current assets	350	232
Total current assets	8,834	36,311
Property and equipment, net	314	407
Restricted cash	119	94
Other assets	—	13
Total assets	$ 9,267	$ 36,825
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,855	$ 1,246
Accrued expenses	1,153	1,794
Notes payable, current portion	—	4,134
Deferred revenue	—	406
Total current liabilities	3,008	7,580
Other liabilities	73	423
Notes payable, net of current portion	—	9,763
Warrant liability	13	115
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized at June 30, 2016 and December 31, 2015 and no shares issued and outstanding at June 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value per share; 200,000,000 shares authorized at June 30, 2016 and December 31, 2015 and 20,005,771 and 19,619,124 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	20	20
Additional paid-in capital	145,420	144,126
Accumulated deficit	(139,267)	(125,202)
Total stockholders' equity	6,173	18,944
Total liabilities and stockholders' equity	$ 9,267	$ 36,825

See accompanying notes.

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	$ 277	$ 114	$ 506	$ 358
Operating expenses:				
Research and development	3,298	6,269	7,930	11,507
General and administrative	3,471	2,247	5,618	4,850
Total operating expenses	6,769	8,516	13,548	16,357
Loss from operations	(6,492)	(8,402)	(13,042)	(15,999)
Other income (expense):				
Other income, net	1	1,826	139	3,134
Loss on extinguishment of debt	—	—	(915)	—
Interest expense	—	(330)	(247)	(565)
Total other income (expense), net	1	1,496	(1,023)	2,569
Net loss and comprehensive loss	$ (6,491)	$ (6,906)	$ (14,065)	$ (13,430)
Net loss per share applicable to common stockholders—basic and diluted	$ (0.33)	$ (0.36)	$ (0.71)	$ (0.72)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	19,874	19,087	19,756	18,532

See accompanying notes.

ELEVEN BIOTHERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2016	**2015**
Operating activities		
Net loss	$ (14,065)	$ (13,430)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	93	192
Non-cash interest expense	26	26
Stock-based compensation expense	1,207	1,266
Change in fair value of warrant liability	(102)	(3,123)
Loss on extinguishment of debt	221	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(126)	(596)
Restricted cash	(25)	—
Accounts payable	609	(578)
Accrued expenses and other liabilities	(991)	(1,209)
Deferred revenue	(406)	(55)
Net cash used in operating activities	(13,559)	(17,507)
Investing activities		
Purchases of property and equipment	—	(286)
Net cash used in investing activities	—	(286)
Financing activities		
Proceeds from issuance of common stock and common stock warrants, net of offering costs	—	12,172
Payments on notes payable	(14,124)	—
Proceeds from notes payable	—	5,000
Proceeds from exercise of common stock options and warrants	88	56
Net cash (used in) provided by financing activities	(14,036)	17,228
Net decrease in cash and cash equivalents	(27,595)	(565)
Cash and cash equivalents at beginning of period	36,079	54,059
Cash and cash equivalents at end of period	$ 8,484	$ 53,494
Supplemental non-cash financing activities		
Issuance of warrants for common stock	—	$ 328
Supplemental cash flow information		
Cash paid for interest	$ 663	$ 374

See accompanying notes.

ELEVEN BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

1. Organization and Basis of Presentation

Eleven Biotherapeutics, Inc. (the "Company"), formerly known as Denovo Therapeutics, Inc. and Newco LS14, Inc., a Delaware corporation formed on February 25, 2008, is a biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. The Company's most advanced product candidate, which is still in preclinical development, is EBI-031, which the Company designed, engineered and generated using its AMP-Rx platform and is developing as an intravitreal injection for diabetic macular edema ("DME") and uveitis. On June 10, 2016, the Company submitted an investigational new drug application ("IND") to the United States Food and Drug Administration ("FDA") to initiate a Phase I clinical trial of its product candidate EBI-031, and the FDA granted clearance of this IND on July 7, 2016 ("IND Clearance").

License Transaction

On June 10, 2016, the Company entered into a License Agreement (the "License Agreement") with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, "Roche"). Under the License Agreement, the Company has agreed to grant Roche an exclusive, worldwide license, including the right to sublicense, to its patent rights and know-how related to the Company's monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product (collectively, the "Licensed Intellectual Property").

Under the License Agreement, Roche will be required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody (a "Licensed Product") at its cost, except that the Company will be responsible, at its cost, for any tissue cross-reactivity studies of EBI-031 that had been initiated before the achievement of IND Clearance.

Financial Terms

Roche has agreed to pay an up-front license fee of $7.5 million within 30 days after the effective date of the license under the License Agreement and receipt of an invoice from the Company, and up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to the Company for the achievement of specified milestones with respect to the first indication: $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment will equal $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, the Company will be entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche further described below.

Buy-Out Options

The License Agreement provides for two "option periods" during which Roche may elect to make a one-time payment to the Company and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing ("Initiation") in the first Phase II study for a Licensed Product until the day before Initiation of the first Phase III study for a Licensed Product, in which case Roche is required to pay the Company $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase III study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a biologics license application ("BLA") or similar application for marketing approval for a Licensed Product in either the United States or in the European Union, in which case Roche is required to pay the Company, within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from the Company, $265 million , which amount would be reduced to $220

million if none of the Company's patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the European Union.

Conditions to Effectiveness

The transactions contemplated by the License Agreement (the "License Transaction") may constitute the sale of all or substantially all of the property and assets of the Company within the meaning of Section 271 of the Delaware General Corporation Law (the "DGCL"). As a result, the Company is seeking approval of the License Transaction from the holders of a majority of its outstanding common stock entitled to vote thereon pursuant to the DGCL. The effectiveness of the license under the License Agreement and the receipt of any upfront payment or potential milestone or royalty payments are each conditioned on obtaining this stockholder approval. A special meeting of stockholders is to be held on August 15, 2016 for the purpose of obtaining stockholder approval.

If the License Transaction is approved by the Company's stockholders, the License Agreement will automatically become effective on the following business day; provided that no governmental entity of competent jurisdiction shall have issued or entered any order, judgment or injunction or statute, rule or regulation which has the effect of prohibiting the consummation of the transactions contemplated by the License Agreement.

Termination

The License Agreement will terminate automatically if the Company fails to obtain approval of the transactions contemplated by the License Agreement by the holders of a majority of its outstanding common stock entitled to vote thereon. The License Agreement may be terminated by Roche if the special meeting of stockholders at which such vote will be taken does not occur within 75 days following execution of the License Agreement. The License Agreement may also be terminated prior to effectiveness by either party if the Company's board of directors has approved or recommended to the stockholders of the Company an alternative strategic transaction with respect to the Licensed Intellectual Property that the Company's board of directors has determined in good faith is, or could reasonably be expected to lead to such an alternative strategic transaction which is, more favorable to the Company or its stockholders than the transactions contemplated by the License Agreement.

The Company or Roche may each terminate the License Agreement if the other party breaches any of its material obligations under the License Agreement and does not cure such breach within a specified cure period. Roche may terminate the License Agreement following effectiveness by providing advance written notice to the Company or by providing written notice if the Company is debarred, disqualified, suspended, excluded, or otherwise declared ineligible from certain federal or state agencies or programs. The Company may terminate the License Agreement if, prior to the first filing of a BLA for a Licensed Product, there is a period of 12 months where Roche is not conducting sufficient development activities with respect to the products made from the Licensed Intellectual Property.

Representations and Warranties and Certain Covenants

The License Agreement contains certain representations and warranties from both the Company and Roche. The License Agreement also contains certain covenants, including covenants requiring the Company to not solicit, initiate or knowingly facilitate or knowingly encourage the submission of any proposals or offers relating to alternative transactions in respect of the Licensed Intellectual Property, or, subject to certain exceptions, to engage in any discussions or negotiations with respect thereto.

Indemnification and Dispute Resolution

The License Agreement contains indemnification and dispute resolution provisions that are customary for agreements of its kind.

Liquidity

The Company has financed its operations to date primarily through private placements of its common stock and preferred stock and convertible bridge notes, venture debt borrowings and its initial public offering ("IPO"), and as of June 30, 2016 , the Company had cash and cash equivalents totaling approximately $8.5 million , net working capital of $5.8 million and an accumulated deficit of $139.3 million . In January 2016, as a result of the outcome of the Company's Phase 3 clinical trial of its lead product candidate, isunakinra (EBI-005), for the treatment of severe allergic conjunctivitis, the Company was required to fund a cash collateral account with Silicon Valley Bank ("SVB") in an amount equal to approximately $15.1 million , representing the outstanding obligations under the Loan and Security Agreement with SVB dated May 27, 2010, as amended on September 4, 2012, November 25, 2014 and December 4, 2015 (the "Loan Agreement"). In March 2016, the Company prepaid all outstanding amounts owed to SVB and terminated the Loan Agreement with existing cash on hand.

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms. These factors raise substantial doubt about the Company's ability to continue as a going concern. In order for the Company to continue operations beyond 2016 and be able to discharge its liabilities and commitments in the normal course of business, the Company has taken or will take the following steps, not all of which are entirely within the Company's control:

- The Company entered into the License Agreement with Roche, which, subject to effectiveness, would provide meaningful cash resources to the Company.

- The Company is engaged in a review of strategic alternatives with a goal of maximizing stockholder value.The Company cannot provide any commitment regarding precisely when or if this strategic review process will result in any type of additional transaction and no assurance can be given that the Company will determine to pursue a potential sale, strategic partnership, business combination or other arrangement.

- The Company does not see an immediate path forward for isunakinra and has implemented a plan to wind down the development activities associated with isunakinra.

- The Company has conducted a review of its operations and implemented a plan to reduce operating expenses to align with current operating conditions, including the workforce reduction described in Note 8 below.

- On March 1, 2016, the Company prepaid all outstanding amounts owed to SVB under the Loan Agreement. The Company continues to evaluate other financing alternatives to provide additional working capital on terms that are consistent with the Company's business plans.

The Company believes that its cash and cash equivalents of $8.5 million as of June 30, 2016 , together with the aggregate upfront and initial milestone payments of approximately $30 million that will be due and payable within 30 days after effectiveness of the License Agreement with Roche, will be sufficient to fund the Company's current operating plan into 2017. If the Company is unable to obtain stockholder approval of the License Transaction and the License Agreement with Roche does not become effective or the Company is unable to obtain other adequate financing or engage in another strategic transaction on acceptable terms and when needed, the Company will be required to implement further cost reduction strategies. These factors and the factors described above continue to raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

These financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP").

2. Significant Accounting Policies

Unaudited interim financial information

Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. Accordingly, these interim condensed financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 10-K").

The condensed financial statements as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 and the related information contained within the notes to the financial statements are unaudited. The unaudited financial statements have been prepared on the same basis as the annual audited financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position as of June 30, 2016 , the statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015 and the statement of cash flows for the six months ended June 30, 2016 and 2015. The results for the three and six months ended June 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, or any other future annual or interim periods.

Net loss per share

Basic net loss per share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock, restricted stock units and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share was the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share applicable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect or the exercise prices were greater than the average market price of the common shares.

	As of June 30,	
	2016	2015
Stock options	2,205,774	2,060,334
Unvested restricted stock	31,010	71,310
Restricted stock units	77,133	211,400
Common stock warrants	926,840	926,840
	3,240,757	3,269,884

There have been no material changes to the significant accounting policies previously disclosed in the 2015 10-K.

Recent Accounting Pronouncements

In the second quarter of 2014, the Financial Accounting Standards Board ("FASB") issued guidance applicable to revenue recognition that will be effective for the Company for the year ending December 31, 2018. The new guidance must be adopted using either a full retrospective approach for all periods presented or a modified retrospective approach. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. The new guidance applies a more principles-based approach to recognizing revenue. The Company is evaluating the new guidance and the expected effect on the Company's financial statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Going Concern (Subtopic 205-40) ("ASU 2014-15"). ASU 2014-15 requires management of all entities to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable). The guidance is effective for fiscal years ending after December 15, 2016 and for interim periods after that fiscal year. The Company does not expect the adoption of this guidance to have a material effect on the Company's financial statements, but may require further disclosure in its financial statements once adopted.

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, Balance Sheet Classification of Deferred Taxes ("ASU 2015-17"). ASU 2015-17 requires companies to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. The guidance is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. The guidance may be adopted on either a prospective or retrospective basis. The Company does not expect the adoption of this guidance to have a material effect on the Company's financial statements.

In February 2016, the FASB issued Accounting Standard Update No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 addresses the financial reporting of leasing transactions. Under current guidance for lessees, leases are only included on the balance sheet if certain criteria, classifying the agreement as a capital lease, are met. This update will require the recognition of a right-of-use asset and a corresponding lease liability, discounted to the present value, for all leases that extend beyond 12 months. For operating leases, the asset and liability will be expensed over the lease term on a straight-line basis, with all cash flows included in the operating section of the statement of cash flows. For finance leases, interest on the lease liability will be recognized separately from the amortization of the right-of-use asset in the statement of operations and the repayment of the principal portion of the lease liability will be classified as a financing activity while the interest component will be included in the operating section of the statement of cash flows. This guidance is effective for annual and interim reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company has not yet completed the analysis of how adopting this guidance will affect its financial statements.

In March 2016, the FASB issued Accounting Standard Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas of simplification apply only to nonpublic entities. For public business entities, the amendments in ASU 2016-09 are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. For all other entities, the amendments are effective for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Early adoption is permitted for any entity in any interim or annual period for which financial statements haven't been issued or made available for issuance. If an entity early adopts the amendments in an interim period, any adjustments must be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company has not yet completed the analysis of how adopting this guidance will affect its financial statements.

3. Fair Value of Financial Instruments

The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value, and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value. The Company determines the fair value of the common stock warrants using Level 3 inputs.

The following table summarizes the assets measured at fair value on a recurring basis at June 30, 2016 (in thousands):

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 8,484	$ 8,484	$ —	$ —
Total	$ 8,484	$ 8,484	$ —	$ —

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 13	$ —	$ —	$ 13
Total	$ 13	$ —	$ —	$ 13

The following table summarizes the assets and liabilities measured at fair value on a recurring basis at December 31, 2015 (in thousands):

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 36,079	$ 36,079	$ —	$ —
Total	$ 36,079	$ 36,079	$ —	$ —

Description	Total	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Liabilities:				
Warrant liability	$ 115	$ —	$ —	$ 115
Total	$ 115	$ —	$ —	$ 115

The Company measures the fair value of the warrants classified as a liability at each reporting date using the Black-Scholes option pricing model using the following assumptions:

	June 30, 2016	December 31, 2015
Risk-free interest rate	0.52%	1.06%
Expected dividend yield	—%	—%
Expected term (in years)	1.42	1.92
Expected volatility	79.43%	70.67%

The following table sets forth a summary of changes in the fair value of the Company's common stock warrant liability, which represented a recurring measurement classified within Level 3 of the fair value hierarchy, wherein fair value was estimated using significant unobservable inputs (in thousands):

Beginning balance, January 1, 2016	$ 115
Change in fair value	(102)
Ending balance, June 30, 2016	$ 13

The change in the fair value of the warrant liability is primarily influenced by the price of the underlying common stock.

There have been no changes to the valuation methods utilized during the three and six months ended June 30, 2016 . The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the three and six months ended June 30, 2016 .

4. Collaboration Agreement

On May 28, 2013 , the Company entered into the collaboration and license agreement (the "Collaboration and License Agreement") with ThromboGenics N.V. ("ThromboGenics"). Under the Collaboration and License Agreement, the Company and ThromboGenics collaborated to seek to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. In connection with the Collaboration and License Agreement, ThromboGenics paid the Company an upfront technology licensing fee of $1.75 million and paid the Company to perform activities under the Collaboration and License Agreement at a set rate per full-time equivalent person working on collaboration activities. The initial research term concluded in November 2015, however it was amended at that time to extend the performance period into 2016. The Collaboration and License Agreement provides for potential future payments to the Company upon achievement of specified preclinical, clinical and regulatory milestones with respect to collaboration products and royalties on sales of collaboration products by ThromboGenics, its affiliates or sublicensees. However, as there have not been any collaboration products identified whose modulation of any of the targets has been confirmed in the course of the research conducted under the Collaboration and License Agreement, none of these milestones or royalties are expected to be payable. On August 1, 2016, the Company received notice from ThromboGenics of ThromboGenics's termination, effective as of October 31, 2016, of the Collaboration and License Agreement.

The Company accounts for this agreement pursuant to ASC Topic 605-25, *Revenue Recognition - Multiple Element Arrangements* , or ASC 605-25. The Company was recognizing the arrangement consideration using the proportional performance method, by which the amounts are recognized in proportion to the costs incurred based on full time equivalent personnel efforts. Subsequent to the amendment in November 2015, the Company is recognizing revenue on a straight-line basis over the remaining performance period. For the three and six month periods ended June 30, 2016, the Company recognized $0.2 million and 0.4 million included in revenue in the consolidated statement of operations. No further amounts are expected to be recognized in the future. The costs incurred by the Company related to the research activities are recorded as research and development expense in the statement of operations and comprehensive loss.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Development costs	$ 160	$ 931
Employee compensation	915	573
Professional fees	77	194
Interest	—	88
Other	1	8
	$ 1,153	$ 1,794

6. Share-Based Payments

In December 2013, the Company's 2014 Stock Incentive Plan (the "2014 Plan") was adopted by the Board of Directors and approved by the Company's stockholders in January 2014. Pursuant to the terms of the plan, the number of shares authorized for issuance automatically increases on the first day of each fiscal year. On January 1, 2016 and 2015, the number of shares reserved for issuance under the 2014 Plan increased by 786,431 and 722,331 shares, respectively. As of June 30, 2016 , the total number of shares of common stock available for issuance under the 2014 Plan was 618,988 .

The Company also maintains the Eleven Biotherapeutics, Inc. 2009 Stock Incentive Plan, as amended and restated.

Stock-Based Compensation Expense

Stock-based compensation expense by award type was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Stock options	$ 444	$ 598	$ 879	$ 1,234
Restricted stock	51	4	105	32
Restricted stock units	106	—	198	—
Performance stock options	14	—	14	—
Employee stock purchase plan	6	—	11	—
	$ 621	$ 602	$ 1,207	$ 1,266

At June 30, 2016 , there was $3.1 million of total unrecognized compensation expense, net of estimated forfeitures, related to non-vested stock options, unvested restricted stock, restricted stock units (each with service-based vesting provisions), and shares issued pursuant to the Company's 2014 Employee Stock Purchase Plan (the "ESPP"). This unrecognized compensation expense is expected to be recognized over a weighted-average period of 1.85 years.

The Company has granted stock options to the founders and officers of the Company, which contain both performance-based and service-based vesting criteria. Milestone events are specific to the Company’s corporate goals, including but not limited to certain preclinical and clinical development milestones related to the Company’s product candidates. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance condition is

considered probable of achievement using management's best estimates. On June 15, 2016 the Compensation Committee of the Company determined that the Company had achieved a milestone event on June 10, 2016 and the Company recorded $14,000 of expense during the three and six months ended June 30, 2016 associated with the achievement of that milestone. There was no expense recorded for performance-based vesting awards during the three and six months ended June 30, 2015 . The remaining milestones were not deemed to be probable of achievement as of June 30, 2016 . As of June 30, 2016 , unrecognized compensation expense related to performance based awards was $28,000 .

Stock Options

A summary of the stock option activity is presented below:

	Shares	Weighted-Average Exercise Price
Outstanding at December 31, 2015	1,803,574	$ 6.28
Granted	981,352	0.39
Exercised	(281,441)	0.29
Cancelled or forfeited	(297,711)	3.60
Outstanding at June 30, 2016	2,205,774	$ 4.78
Exercisable at June 30, 2016	891,327	$ 6.05
Vested and expected to vest at June 30, 2016 (1)	1,923,413	$ 5.20

(1) Represents the number of vested options, plus the number of unvested options expected to vest.

Restricted Stock

From time to time, upon approval by the Board of Directors, certain employees, directors and advisors have been granted restricted shares of common stock. A summary of the unvested restricted stock is presented below:

	Restricted Stock	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2015	41,657	$ 11.05
Vested	(10,647)	9.94
Unvested at June 30, 2016	31,010	$ 11.43

Restricted Stock Units

From time to time, upon approval by the Board of Directors, certain employees have been granted restricted stock units. A summary of the restricted stock units is presented below:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2015	150,932	$ 2.85
Vested	(73,799)	2.82
Unvested at June 30, 2016	77,133	$ 2.88

Employee Stock Purchase Plan

On January 21, 2014, the Company's board of directors adopted its 2014 ESPP, which was subsequently approved by its stockholders and became effective upon the closing of the Company's IPO on February 6, 2014. The 2014 ESPP authorizes the

initial issuance of up to a total of 157,480 shares of the Company's common stock to participating employees. The first offering period under the 2014 ESPP opened on September 15, 2015 and closed on March 14, 2016. On March 14, 2016, the Company issued and sold 20,760 shares of its common stock pursuant to the 2014 ESPP at a purchase price of $0.31 per share. The second offering period under the 2014 opened on March 15, 2016.

7. Indebtedness

Term Loan

On March 1, 2016, the Company prepaid all outstanding amounts owed to SVB under the Loan Agreement. These obligations included the outstanding principal and interest of $13.8 million and a prepayment penalty of $0.2 million . In addition, the Company was required to pay a final payment equal to 6% of the amounts borrowed under the Loan Agreement, or $0.9 million , of which $0.4 million was accrued as of March 1, 2016. In addition, as a result of the prepayment, the Company wrote off the unamortized debt issuance costs and debt discount of $0.2 million . In connection with the prepayment, the Company has recorded a loss on extinguishment of debt of $ 0.9 million , which is included in other expense on the condensed statement of operations and comprehensive loss for the six months ending June 30, 2016 .

8. Reduction in Workforce

On June 16, 2016, the Board of Directors (the "Board") of the Company approved a strategic restructuring of the Company to eliminate a portion of the Company's workforce in order to preserve the Company's resources as it determines future strategic plans.

As part of this strategic restructuring, the Company will eliminate 14 positions across the organization, representing approximately 70% of the Company's workforce. The Company expects the restructuring to be substantially complete in the third quarter of 2016. The Company incurred total restructuring costs of approximately $0.6 million , which includes severance, benefits and related costs in accordance with the Company's severance benefit plan. As the Company determined the severance was a continuation of a benefit arrangement with employees, the Company recorded the total $0.6 million of restructuring charges as $0.1 million in general and administrative expenses and $0.5 million in research and development expenses within the Condensed Statement of Operations and Comprehensive Loss for the three and six months ended June 30, 2016 . None of these restructuring charges have been paid as of June 30, 2016 and approximately $0.6 million remains as an accrued liability in the Condensed Balance Sheet as of June 30, 2016 .

9. Subsequent Events

On August 1, 2016, the Company received notice from ThromboGenics of ThromboGenics's termination, effective as of October 31, 2016, of the Collaboration and License Agreement.

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 in conjunction with our financial statements and the notes to those financial statements appearing in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2015 (the "2015 10-K"). This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item IA, "Risk Factors" of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements.

Overview

We are a preclinical stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that we apply to the discovery and development of protein therapeutics to treat diseases of the eye. Our therapeutic approach is based on the role of cytokines in diseases of the eye, our understanding of the structural biology of cytokines and our ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. Our most advanced product candidate, which is still in preclinical development, is EBI-031, which we designed, engineered and generated using our AMP-Rx platform and are developing as an intravitreal injection for diabetic macular edema, or DME, and uveitis. On June 10, 2016, we submitted an investigational new drug application, or IND, to the United States Food and Drug Administration, or FDA, to initiate a Phase I clinical trial of EBI-031, and the FDA granted clearance of this IND, which we refer to as IND Clearance, on July 7, 2016. We currently hold worldwide commercialization rights to EBI-031.

We previously invested a significant portion of our efforts and financial resources in the development of our product candidate isunakinra (EBI-005) for the treatment of patients with dry eye disease and allergic conjunctivitis. Notwithstanding this significant investment, based on the negative results from our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra.

We were incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. To date, we have financed our operations primarily through private placements of our common stock and preferred stock and convertible bridge notes, venture debt borrowings and our initial public offering, or IPO, sales effected in an "at the market" offering through our agent, Cowen and Company, LLC, or Cowen, and, to a lesser extent, from a collaboration. Substantially all of our revenue to date has been collaboration revenue, which we first began to generate in 2013. We have devoted substantially all of our financial resources and efforts to research and development activities. We are still in the early stages of development of our product candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

Since inception, we have incurred significant operating losses. Our net loss was $14.1 million for the six months ended June 30, 2016 , $33.5 million for the year ended December 31, 2015, $34.2 million for the year ended December 31, 2014 and $18.0 million for the year ended December 31, 2013. As of June 30, 2016 , we had an accumulated deficit of $139.3 million .

License Agreement with Roche

On June 10, 2016, we entered into a License Agreement, which we refer to as the License Agreement, with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche. Under the License Agreement, we have agreed to grant Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product, or collectively, Licensed Intellectual Property.

Pursuant to the terms of the License Agreement, Roche will be required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody, or Licensed Product, at its cost, except that we will be responsible, at our cost, for any tissue cross-reactivity studies of EBI-031 that we initiated before the achievement of IND Clearance.

Financial Terms

Roche has agreed to pay an up-front license fee of $7.5 million within 30 days after the effective date of the license under the License Agreement and receipt of an invoice from us, and up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment will equal $22.5 million as a result of the IND application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we would be entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche further described below.

Buy-Out Options

The License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing, or Initiation, in the first Phase II study for a Licensed Product until the day before Initiation of the first Phase III study for a Licensed Product, in which case Roche is required to pay us $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from us, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase III study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a biologics license application, or BLA, or similar application for marketing approval for a Licensed Product in either the United States or in the European Union, in which case Roche is required to pay us, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, $265 million, which amount would be reduced to $220 million if none of our patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the European Union.

Conditions to Effectiveness

The transactions contemplated by the License Agreement, or License Transaction, may constitute the sale of all or substantially all of our property and assets within the meaning of Section 271 of the Delaware General Corporation Law, or DGCL. As a result, we are seeking approval of the License Transaction from the holders of a majority of our outstanding common stock entitled to vote thereon pursuant to the DGCL. The effectiveness of the license under the License Agreement and the receipt of any upfront payment or potential milestone or royalty payments are each conditioned on obtaining this stockholder approval. A special meeting of stockholders is scheduled to be held on August 15, 2016 for the purpose of obtaining this stockholder approval.

If the License Transaction is approved by our stockholders, the License Agreement will automatically become effective on the following business day; provided that no governmental entity of competent jurisdiction shall have issued or entered any order, judgment or injunction or statute, rule or regulation which has the effect of prohibiting the consummation of the transactions contemplated by the License Agreement.

Termination

The License Agreement will terminate automatically if we fail to obtain approval of the transactions contemplated by the License Agreement by the holders of a majority of our outstanding common stock entitled to vote thereon. The License Agreement may be terminated by Roche if the special meeting of stockholders at which such vote will be taken does not occur within 75 days following execution of the License Agreement. The License Agreement may also be terminated prior to effectiveness by either party if our board of directors has approved or recommended to our stockholders an alternative strategic transaction with respect to the Licensed Intellectual Property that our board of directors has determined in good faith is, or could reasonably be expected to lead to such an alternative strategic transaction which is, more favorable to us or our stockholders than the transactions contemplated by the License Agreement.

We or Roche may each terminate the License Agreement if the other party breaches any of its material obligations under the License Agreement and does not cure such breach within a specified cure period. Roche may terminate the License Agreement following effectiveness by providing advance written notice to us or by providing written notice if we are debarred, disqualified, suspended, excluded, or otherwise declared ineligible from certain federal or state agencies or programs. We may terminate the License Agreement if, prior to the first filing of a BLA for a Licensed Product, there is a period of twelve months

where Roche is not conducting sufficient development activities with respect to the products made from the Licensed Intellectual Property.

Representations and Warranties and Certain Covenants

The License Agreement contains certain representations and warranties from both us and Roche. The License Agreement also contains certain covenants, including covenants requiring us to not solicit, initiate or knowingly facilitate or knowingly encourage the submission of any proposals or offers relating to alternative transactions in respect of the Licensed Intellectual Property, or, subject to certain exceptions, to engage in any discussions or negotiations with respect thereto.

Indemnification and Dispute Resolution

The License Agreement contains indemnification and dispute resolution provisions that are customary for agreements of its kind.

Strategic Alternatives

Although the License Transaction may be deemed to constitute the "sale" of "all or substantially all" of our assets and property under the DGCL, following effectiveness of the License Transaction we will retain rights to our intellectual property and assets other than the Licensed Intellectual Property, including the retention of rights to the other early stage product candidates in our pipeline. We will also retain rights to our AMP-Rx proprietary protein engineering platform that we have used to discover and develop innovative protein therapeutics to treat diseases of the eye. However, we continue to engage in a process to review a range of strategic alternatives with the goal of maximizing stockholder value. Further, most of our research and development activities, other than with respect to EBI-031, are on hold pending the outcome of this strategic review process as we seek to manage our cash position. As such, our business efforts are currently devoted primarily to our review of strategic alternatives. Potential strategic alternatives that we may continue to explore and evaluate during the ongoing review process include, among others, the sale of the Company, a strategic partnership or a business combination with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies that are not related to the License Agreement. We cannot provide any commitment regarding precisely when or if this strategic review process will result in any type of additional transaction and no assurance can be given that we will determine to pursue a potential sale, strategic partnership, business combination or other arrangement.

As part of the strategic review process, or if the strategic review process does not result in any additional transaction, we may also consider a distribution to our stockholders of all or a portion of the payments from Roche under the License Agreement. We expect to consider a variety of factors in making any decision to distribute to our stockholders all or a portion of the payments from Roche under the License Agreement as part of another strategic transaction, with the goal of maximizing stockholder value. In particular, we may be more likely to consider a distribution to our stockholders of some or all of the cash proceeds under the License Agreement, some or all of the rights to receive future payments under the License Agreement or a combination thereof if the third parties with whom we may negotiate potential transactions, such as a sale of the Company or a business combination, ascribe less value to potential future payments under the License Agreement than does our board of directors, including if the proposed ownership percentage of our stockholders following a proposed business combination does not reflect what our board of directors believes is appropriate value when compared with such a distribution to our stockholders. Conversely, if we believe that a proposed ownership percentage of our stockholders following a business combination reflects appropriate value with respect to the potential future payments under the License Agreement, including because of the relative value such ownership percentage would represent following such business combination, we may consummate the business combination without distributing to our stockholders any of the payments or rights to receive future payments under the License Agreement. In addition, a third party may require as a condition to the consummation of a transaction that we retain a minimum amount of cash resources upon the closing of such transaction, which would limit our ability to distribute cash or the right to receive future payments under the License Agreement to our stockholders if our board of directors otherwise determines such a transaction is favorable to our stockholders. If our strategic review process does not result in any additional transaction before the end of 2016 (or such earlier time as our board of directors determines to end the strategic review process), we may be inclined to distribute a significant portion of amounts received from Roche and the right to receive future payments from Roche under the License Agreement to our stockholders via a dividend in the form of a contractual right to a pro rata share of such payments. Any such distribution to our stockholders would reduce funds potentially available to contribute to our future business operations and likely result in a decrease in the value of the Company immediately following the payment of any such distribution. Any such distribution via dividend could be followed by a potential dissolution of the Company, subject to approval by our stockholders. We may also consider additional arrangements to
return capital to our stockholders if our strategic review process does not result in any additional transaction.

Liquidity

We are devoting substantial financial resources to our ongoing and planned activities, including to functions associated with operating as a public company. We also may devote additional financial resources to conducting research and development if we determine to proceed into clinical development, initiating clinical trials of, and seeking regulatory approval for, our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales and distribution. 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 could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our future success is dependent on our ability to develop our product candidates and ultimately upon our ability to attain profitable operations. We are subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of our drug candidates, raising additional capital, development by our competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. These factors raise substantial doubt about our ability to continue as a going concern. In order for us to continue operations beyond 2016 and be able to discharge our liabilities and commitments in the normal course of business, we have taken or will take the following steps, not all of which are entirely within our control:

- We entered into the License Agreement with Roche, which, subject to effectiveness, would provide meaningful cash resources to us.
- We are engaged in a review of strategic alternatives with the goal of maximizing stockholder value. We cannot provide any commitment regarding precisely when or if this strategic review process will result in any type of additional transaction and no assurance can be given that we will determine to pursue a potential sale, strategic partnership, business combination or other arrangement.
- We do not see an immediate path forward for isunakinra and have implemented a plan to wind down the development activities associated with isunakinra.
- We have conducted a review of our operations and implemented a plan to reduce future operating expenses to align with current operating conditions, including the workforce reduction described in Note 8 to our Condensed Financial Statements included in this Quarterly Report on Form 10-Q.
- On March 1, 2016, we prepaid all outstanding amounts owed to Silicon Valley Bank, or SVB, under our Loan and Security Agreement with SVB. We continue to evaluate other financing alternatives to provide additional operating funds on terms that are consistent with our business plans.

We believe that our cash and cash equivalents of $8.5 million as of June 30, 2016, together with the aggregate upfront and initial milestone payments of approximately $30 million that will be due and payable within 30 days after effectiveness of the License Agreement with Roche, will be sufficient to fund our current operating plan into 2017. If we are unable to obtain stockholder approval of the License Transaction and the License Agreement with Roche does not become effective or we are unable to obtain other adequate financing or engage in another strategic transaction on acceptable terms and when needed, we will be required to implement further cost reduction strategies. These factors, and the factors described above, continue to raise substantial doubt about our ability to continue as a going concern. In its report on our financial statements for the year ended December 31, 2015, our independent registered public accounting firm has included an explanatory paragraph about our ability to continue as a going concern.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from the sale of products. Substantially all of our revenue to date has been derived from a collaboration and, to a lesser extent, from a license agreement. We do not expect to generate significant product revenue unless and until we obtain marketing approval for, and commercialize our product candidates.

We have generated collaboration revenue exclusively from our collaboration and license agreement with ThromboGenics N.V., or ThromboGenics, which we entered into in May 2013. Under the agreement, we and ThromboGenics collaborated to seek to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. In connection with the agreement, ThromboGenics paid us an upfront technology licensing fee of $1.75 million and paid us to perform activities under the agreement at a set rate per full-time equivalent person working on collaboration activities. The initial research term concluded in November 2015, however it was amended at that time to extend the

performance period into 2016. The agreement provides for potential future payments to us upon achievement of specified preclinical, clinical and regulatory milestones with respect to collaboration products and royalties on sales of collaboration products by ThromboGenics, its affiliates or sublicensees. However, as there have not been any collaboration products identified whose modulation of any of the targets has been confirmed in the course of the research conducted under the agreement, none of these milestones or royalties are expected to be payable. On August 1, 2016, we received notice from ThromboGenics of ThromboGenics's termination, effective as of October 31, 2016, of the agreement.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- expenses associated with developing manufacturing capabilities and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies; and
- expenses associated with preclinical and regulatory activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

The successful development and commercialization of any product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our clinical trials and other research and development activities;
- the efficacy and potential advantages of our product candidates compared to alternative treatments, including any standard of care;
- the market acceptance of our product candidates;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation; and
- the timing, receipt and terms of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of any product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond those that we currently contemplate will be required for the completion of clinical development of any product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

We allocate direct research and development expenses, consisting principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to manufacturing or purchasing clinical trial materials, to specific product programs. We do not allocate employee and contractor-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified. The table below provides research and development expenses incurred for our isunakinra and EBI-031 product programs and other expenses by category. We did not allocate research and development expenses to any other specific product program during the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(in thousands)			
Programs:				
Isunakinra	$ 208	$ 4,372	$ 1,530	$ 7,423
EBI-031	1,013	398	2,752	826
Total program expenses	1,221	4,770	4,282	8,249
Personnel and other expenses:				
Employee and contractor-related expenses	1,716	1,067	2,900	2,335
Platform-related lab expenses	102	151	239	340
Facility expenses	163	128	310	237
Other expenses	96	153	199	346
Total personnel and other expenses	2,077	1,499	3,648	3,258
Total research and development expenses	$ 3,298	$ 6,269	$ 7,930	$ 11,507

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation, in executive, operational, finance, business development and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for legal, patent, consulting and accounting services.

Other Income (Expense), Net

Other income and expense consists primarily of interest income earned on cash and cash equivalents, interest expense on outstanding debt, the loss on extinguishment of our debt, and the gain or loss associated with the change in the fair value of our warrant liability.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and significant judgments and estimates from those previously disclosed in the 2015 10-K.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,		
	2016	2015	Change
		(in thousands)	
Revenue	$ 277	$ 114	$ 163
Operating expenses:			
Research and development	3,298	6,269	(2,971)
General and administrative	3,471	2,247	1,224
Total operating expenses	6,769	8,516	(1,747)
Loss from operations	(6,492)	(8,402)	1,910
Other income, net	1	1,496	(1,495)
Net loss	$ (6,491)	$ (6,906)	$ 415

Revenue . Revenue was $0.3 million for the three months ended June 30, 2016 compared to $0.1 million the three months ended June 30, 2015 .

Research and development expenses . Research and development expenses were $3.3 million for the three months ended June 30, 2016 compared to $6.3 million for the three months ended June 30, 2015 . The decrease of $3.0 million was primarily due to a decrease of $4.2 million of isunakinra-related development expenses, which development activities are no longer ongoing. This decrease in isunakinra-related development expenses was partially offset by increases in EBI-031 related development expenses of $0.6 million . In late 2015, we began undertaking the necessary CMC development work and nonclinical safety studies to support the submission of an IND for EBI-031 to the FDA in June 2016. In addition, employee and contractor-related expenses, including stock-based compensation, were $1.7 million for the three months ended June 30, 2016 compared to $1.1 million for the three months ended June 30, 2015.

General and administrative expenses . General and administrative expenses were $3.5 million for the three months ended June 30, 2016 compared to $2.2 million for the three months ended June 30, 2015 . The increase of $1.2 million was primarily due to increased professional fees related to the License Agreement with Roche and our review of strategic alternatives.

Other income, net . Other income, net was $0.0 million for the three months ended June 30, 2016 compared to $1.5 million for the three months ended June 30, 2015 . The decrease of $1.5 million was due to the decrease in the fair value of our warrant liability of $1.8 million in 2015 compared to $0.0 million in 2016 partially offset by the decrease in interest expense of $0.3 million for the three months ended June 30, 2016 compared to the three months ended June 30, 2015.

Comparison of the Six Months Ended June 30, 2016 and 2015

	Six Months Ended June 30,		
	2016	2015	Change
		(in thousands)	
Revenue	$ 506	$ 358	$ 148
Operating expenses:			
Research and development	7,930	11,507	(3,577)
General and administrative	5,618	4,850	768
Total operating expenses	13,548	16,357	(2,809)
Loss from operations	(13,042)	(15,999)	2,957
Other (expense) income, net	(1,023)	2,569	(3,592)
Net loss	$ (14,065)	$ (13,430)	$ (635)

Revenue . Revenue was $0.5 million for the six months ended June 30, 2016 compared to $0.4 million for the six months ended June 30, 2015 .

Research and development expenses . Research and development expenses were $7.9 million for the six months ended June 30, 2016 compared to $11.5 million for the six months ended June 30, 2015 . The decrease of $3.6 million was primarily due to a

decrease of $5.9 million of isunakinra-related development expenses, which was partially offset by increases in EBI-031 related development expenses of $1.9 million . In addition, employee and contractor-related expenses, including stock-based compensation, were $2.9 million for the six months ended June 30, 2016 compared to $2.3 million for the six months ended June 30, 2015.

General and administrative expenses . General and administrative expenses were $5.6 million for the six months ended June 30, 2016 compared to $4.9 million for the six months ended June 30, 2015 . The increase of $0.8 million was primarily due to increased professional fees related to the License Agreement with Roche and our review of strategic alternatives.

Other (expense) income, net . Other (expense) income, net was $(1.0) million for the six months ended June 30, 2016 compared to $2.6 million for the six months ended June 30, 2015 . The change of $(3.6) million was due to the decrease in the fair value of our warrant liability from $3.1 million in 2015 to $0.1 million in 2016. In addition, there was a loss on extinguishment of debt in 2016 of $0.9 million associated with the prepayment of the loan with SVB. These changes were partially offset by a decrease in interest expense from $0.6 million in 2015 to $0.2 million in 2016.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred significant operating losses. Substantially all of our revenue to date has been collaboration revenue and, to a lesser extent, from a licensing agreement. To date, we have financed our operations primarily through private placements of our common stock, preferred stock and bridge notes convertible into our preferred stock, venture debt borrowings, our IPO, sales effected in an "at the market" offering through our agent, Cowen, and, to a lesser extent, from a collaboration.

In March 2015, we entered into a sales agreement, or the Sales Agreement, with Cowen, pursuant to which we may issue and sell shares of our common stock from time to time having an aggregate offering price of up to $40 million through Cowen, acting as our agent. Sales of our common stock through Cowen may be made by any method permitted that is deemed an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made directly on or through the NASDAQ Global Market, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Cowen is not required to sell any specific amount, but acts as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices.

Shares sold pursuant to the Sales Agreement have been sold pursuant to a shelf registration statement, or the 2015 Shelf, which became effective on March 20, 2015 (File No 333-202676), as supplemented by a prospectus supplement dated March 11, 2015. Under the Sales Agreement, we pay Cowen a commission of up to 3% of the gross proceeds. As of June 30, 2016 , we had sold approximately 1,446,781 shares pursuant to the Sales Agreement, resulting in proceeds of approximately $12.7 million, net of commissions and issuance costs.

In November 2014, we amended our Loan and Security Agreement, or the Loan Agreement, with SVB to increase the amount we could borrow to $15.0 million. We borrowed $10.0 million in 2014, and we borrowed the remaining $5.0 million in May 2015. In December 2015, we amended the Loan Agreement to change the repayment terms of the Loan Agreement under specified circumstances and to change the circumstances under which we were required to fund a cash collateral account with SVB in an amount equal to the outstanding amount under the Loan Agreement. As a result of the outcome of our Phase 3 clinical trial of isunakinra for the treatment of severe allergic conjunctivitis, we were required to fund a cash collateral account with SVB in an amount equal to approximately $15.1 million, representing the outstanding obligations under the Loan Agreement. On March 1, 2016, we prepaid all outstanding amounts owed to SVB, in an amount equal to approximately $14.9 million, and terminated the Loan Agreement.

In June 2016, we entered into the License Agreement with Roche. Subject to effectiveness, Roche has agreed to pay an up-front license fee of $7.5 million within 30 days after the effective date of the license under the License Agreement and receipt of an invoice from us, and up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment will equal $22.5 million as a result of the IND for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we would be entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche.

Cash Flows

As of June 30, 2016 , we had cash and cash equivalents of $8.5 million . Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended June 30,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (13,559)	$ (17,507)
Investing activities	—	(286)
Financing activities	(14,036)	17,228
Net decrease in cash and cash equivalents	$ (27,595)	$ (565)

Operating activities. Net cash used in operating activities was $13.6 million for the six months ended June 30, 2016 , and consisted primarily of a net loss of $14.1 million adjusted for non-cash items, including stock-based compensation expense of $1.2 million , depreciation expense of $0.1 million , a change of $(0.1) million in the fair value of the warrant liability, $0.2 million loss on extinguishment of debt and a net change in operating assets and liabilities of $(0.9) million .

Net cash used in operating activities was $17.5 million for the six months ended June 30, 2015 , and consisted primarily of a net loss of $13.4 million adjusted for non-cash items, including stock-based compensation expense of $1.3 million , depreciation expense of $0.2 million , a change of $(3.1) million in the fair value of the warrant liability and a net change in operating assets and liabilities of $(2.4) million .

Investing activities . Net cash used in investing activities consists of purchases of property and equipment. For the six months ended June 30, 2016 and 2015 , we purchased none and $0.3 million of property and equipment, respectively.

Financing activities . Net cash used in financing activities for the six months ended June 30, 2016 was $14.0 million and consisted primarily of repayment of outstanding debt obligations. On March 1, 2016, we prepaid all outstanding amounts owed to SVB and terminated the Loan Agreement.

Net cash provided by financing activities for the six months ended June 30, 2015 was $17.2 million and consisted primarily of net proceeds of $12.2 million from the issuance of common stock in connection with sales effected in an "at the market" offering through our agent , Cowen, and $5.0 million from additional borrowings under our loan with SVB.

Funding Requirements

We will incur substantial expenses if and as we:

- continue the research and development of our preclinical product candidates;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;

- hire additional clinical, quality control, scientific and management personnel; and
- expand our operational, financial and management systems and personnel.

We believe that our cash and cash equivalents of $8.5 million as of June 30, 2016, together with the aggregate upfront and initial milestone payments of approximately $30 million that will be due and payable within 30 days after effectiveness of the License Agreement with Roche, will be sufficient to fund our current operating plan into 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- effectiveness of the License Agreement with Roche;
- the outcome and timing of our review of a range of strategic alternatives with the goal of maximizing stockholder value;
- the scope, progress, results and costs of preclinical development, laboratory testing and, if we determine to proceed into clinical development, clinical trials of our preclincal product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire rights to other products, product candidates or technologies.

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, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts payable under the License Agreement with Roche, subject to the effectiveness thereof. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On March 1, 2016, we prepaid all outstanding amounts owed to SVB and terminated the Loan Agreement.

The following table summarizes our contractual obligations as of June 30, 2016 :

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations(1)	$ 1,229	$ 666	$ 563	$ —	$ —
Total fixed contractual obligations	$ 1,229	$ 666	$ 563	$ —	$ —

(1) We lease office space at 215 First Street in Cambridge, Massachusetts under a non-cancellable operating lease that expires on April 30, 2018.

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 in the rules and regulations of the Securities and Exchange Commission, or SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes to our exposure to market risk from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 as filed with the SEC on March 25, 2016.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2016 . The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e)) under the Exchange Act, means controls and other procedures of a company that are 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 recorded, processed, summarized and reported, within the time period 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, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company's disclosure controls and procedures as of June 30, 2016 , the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Risks Related to the Proposed License Agreement with Roche

The announcement and pendency of the License Transaction with Roche, whether or not consummated, may adversely affect the trading price of our common stock and business prospects.

On June 10, 2016, we entered into a license agreement, which we refer to herein as the License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche. Under the License Agreement, we have agreed to grant Roche an exclusive, worldwide license, including the right to sublicense, to our patent rights and know-how related to our monoclonal antibody EBI-031 or any other IL-6 antagonist anti-IL-6 monoclonal antibody, to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export any product containing such an antibody or any companion diagnostic used to predict or monitor response to treatment with such a product, or collectively, Licensed Intellectual Property.

Pursuant to the terms of the License Agreement, Roche will be required to continue developing EBI-031 and any other product made from the Licensed Intellectual Property that contains an IL-6 antagonist anti-IL-6 monoclonal antibody, or Licensed Product, at its cost, except that we will be responsible, at our cost, for any tissue cross-reactivity studies of EBI-031 that the we initiated before the United States Food and Drug Administration, or FDA, granted us clearance to initiate a Phase I clinical trial of EBI-031, which we refer to herein as IND Clearance.

Roche has agreed to pay an up-front license fee of $7.5 million within 30 days after the effective date of the license under the License Agreement and receipt of an invoice from us, and up to an additional $262.5 million upon the achievement of specified regulatory, development and commercial milestones with respect to up to two unrelated indications. Specifically, an aggregate amount of up to $197.5 million is payable to us for the achievement of specified milestones with respect to the first indication: consisting of $72.5 million in development milestones, $50.0 million in regulatory milestones and $75.0 million in commercialization milestones.

The first development milestone payment will equal $22.5 million as a result of the investigational new drug, or IND, application for EBI-031 becoming effective on or before September 15, 2016. Additional amounts of up to $65.0 million are payable upon the achievement of specified development and regulatory milestones in a second indication.

In addition, we would be entitled to receive royalty payments in accordance with a tiered royalty rate scale, with rates ranging from 7.5% to 15% for net sales of potential future products containing EBI-031 and at up to 50% of these rates for net sales of potential future products containing other IL-6 compounds, with each of the royalties subject to reduction under certain circumstances and to the buy-out options of Roche further described below.

The License Agreement provides for two “option periods” during which Roche may elect to make a one-time payment to us and, in turn, terminate its diligence, milestone and royalty payment obligations under the License Agreement. Specifically, (i) Roche may exercise a buy-out option following the first dosing, or Initiation, in the first Phase II study for a Licensed Product until the day before Initiation of the first Phase III study for a Licensed Product, in which case Roche is required to pay us $135 million within 30 days after Roche's exercise of such buy-out option and receipt of an invoice from us, or (ii) Roche may exercise a buy-out option following the day after Initiation of the first Phase III study for a Licensed Product until the day before the acceptance for review by the FDA or other regulatory authority of a biologics license application, or BLA, or similar application for marketing approval for a Licensed Product in either the United States or in the European Union, in which case Roche is required to pay us, within 30 days after Roche’s exercise of such buy-out option and receipt of an invoice from us, $265 million, which amount would be reduced to $220 million if none of our patent rights containing a composition of matter claim covering any compound or Licensed Product has issued in the European Union.

The transactions contemplated by the License Agreement, or License Transaction, may constitute the sale of all or substantially

all of our property and assets within the meaning of Section 271 of the Delaware General Corporation Law, or DGCL. As a result, we are seeking approval of the transactions contemplated by the License Agreement from the holders of a majority of our outstanding common stock entitled to vote thereon pursuant to the DGCL. The effectiveness of the license under the License Agreement and the receipt of any upfront payment or potential milestone or royalty payments are each conditioned on obtaining this stockholder approval. A special meeting of stockholders is scheduled to be held on August 15, 2016 for the purpose of obtaining this stockholder approval.

If the License Transaction is approved by our stockholders, the License Agreement will automatically become effective on the following business day; provided that no governmental entity of competent jurisdiction shall have issued or entered any order, judgment or injunction or statute, rule or regulation which has the effect of prohibiting the consummation of the transactions contemplated by the License Agreement.

The announcement and pendency of the License Transaction, whether or not consummated, may adversely affect the trading price of our common stock and our business prospects. In the event that the License Transaction is not completed, the announcement of the termination of the License Agreement may also adversely affect the trading price of our common stock and our business prospects.

We cannot be sure if or when the License Transaction will become effective or if it will be delayed and, even if it becomes effective in accordance with its terms, whether we will receive any future payments pursuant to the License Agreement.

The effectiveness of the license under the License Agreement is subject to the authorization of the License Transaction by our stockholders, provided that, in addition, no governmental entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any order, stay, decree, judgment or injunction or statute, rule or regulation which has the effect of prohibiting the consummation of the transactions contemplated by the License Agreement. We cannot guarantee that the License Agreement will become effective. If the License Agreement does not become effective, Roche will not be obligated to consummate the transactions contemplated by the License Agreement, and any delay could materially impair the value we may receive under the License Agreement.

In addition, the right to potential future payments under the License Agreement represents a significant portion of the value of the License Transaction to the Company. Even if the License Transaction is approved by the Company's stockholders and the license under the License Agreement becomes effective in accordance with its terms, we cannot be certain that we will receive any future payments under the License Agreement, which would adversely affect the trading price of our common stock and our business prospects.

We have not made any determination whether to distribute or pay any dividends to stockholders, including with respect to any of the proceeds of the License Agreement.

We have not made any determination whether to distribute or pay any dividends to our stockholders with respect to the up- front, milestone, royalty or any other payments we may receive pursuant to the License Agreement. However, we continue to engage in a process to review a range of strategic alternatives with the goal of maximizing stockholder value. As part of the strategic review process, or if the strategic review process does not result in any additional transaction, we may also consider a distribution to our stockholders of all or a portion of the payments from Roche under the License Agreement. We expect to consider a variety of factors in making any decision to distribute to our stockholders all or a portion of the payments from Roche under the License Agreement as part of another strategic transaction, with the goal of maximizing stockholder value. In particular, we may be more likely to consider a distribution to our stockholders of some or all of the cash proceeds under the License Agreement, some or all of the rights to receive future payments under the License Agreement or a combination thereof if the third parties with whom we may negotiate potential transactions, such as a sale of the Company or a business combination, ascribe less value to potential future payments under the License Agreement than does our board of directors, including if the proposed ownership percentage of our stockholders following a proposed business combination does not reflect what our board of directors believes is appropriate value when compared with such a distribution to our stockholders. Conversely, if we believe that a proposed ownership percentage of our stockholders following a business combination reflects appropriate value with respect to the potential future payments under the License Agreement, including because of the relative value such ownership percentage would represent following such business combination, we may consummate the business combination without distributing to our stockholders any of the payments or rights to receive future payments under the License Agreement. In addition, a third party may require as a condition to the consummation of a transaction that we retain a minimum amount of cash resources upon the closing of such transaction, which would limit our ability to distribute cash or the right to receive future payments under the License Agreement to our stockholders if our board of directors otherwise determines such a transaction is favorable to our stockholders. If our strategic review process does not result in any

additional transaction before the end of 2016 (or such earlier time as our board of directors determines to end the strategic review process), we may be inclined to distribute a significant portion of the right to receive future payments from Roche under the License Agreement to our stockholders via a dividend in the form of a contractual right to a pro rata share of such payments owed to us. Any such distribution to our stockholders would reduce funds potentially available to contribute to our future business operations and likely result in a decrease in the value of the Company immediately following the payment of any such distribution. We may also consider additional arrangements to return capital to our stockholders if our strategic review process does not result in any additional transaction.

The License Agreement limits our ability to pursue alternatives to the License Transaction.

Except as specifically set forth therein, the License Agreement restricts our ability and the ability of our directors, officers, employees and other agents or advisors to solicit, initiate or knowingly facilitate or knowingly encourage the submission of any proposal or offer from any third party with respect to an alternative strategic transaction involving the Licensed Intellectual Property; enter into or participate in any discussions or negotiations with, furnish any non-public information relating to our IL-6 program to, or afford access to the business, properties, assets, books or records of our IL-6 program to, any third party that, to our knowledge, is seeking to make, or has made, any proposal or offer for an alternative strategic transaction, in each case relating to or in connection with an alternative strategic transaction; or enter into any agreement with respect to any such alternative strategic transactions. These limitations could make it more difficult for a third party to have an interest in acquiring the Company or the Licensed Intellectual Property or to consider or propose to us an alternative transaction.

If the License Transaction is not completed, we may not have any comparable offers or alternatives.

If the License Transaction is not completed, our board of directors, in discharging its fiduciary obligations to our stockholders, may evaluate other strategic alternatives, which alternatives may not be as favorable to our stockholders as the License Transaction. These may include retaining and developing the Licensed Intellectual Property on a stand-alone basis or pursuing an alternative transaction that would yield reduced consideration or involve significant delays. Any future sale or disposition of substantially all of the assets of the Company or other potential transactions may be subject to further stockholder approval.

We will continue to incur the expenses of complying with public company reporting requirements following the effectiveness of the License Transaction.

After the effectiveness of the License Transaction, we will continue to be required to comply with the applicable reporting requirements of the Exchange Act, even though compliance with such reporting requirements may be economically burdensome.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $14.1 million for the six months ended June 30, 2016 , $33.5 million for the year ended December 31, 2015, $34.2 million for the year ended December 31, 2014 and $18.0 million for the year ended December 31, 2013. As of June 30, 2016 , we had an accumulated deficit of $139.3 million . To date, we have financed our operations primarily through private placements of our common stock and preferred stock and convertible bridge notes, venture debt borrowings and our initial public offering, or IPO, sales effected in an "at the market" offering through our agent, Cowen and Company, LLC, and, to a lesser extent, from a collaboration. Substantially all of our revenue to date has been collaboration revenue, which we first began to generate in 2013. We have devoted substantially all of our financial resources and efforts to research and development activities. We are still in the early stages of development of our product candidates, and we have not completed development of any drugs. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We will incur substantial expenses if and as we:

- continue the research and development of our preclinical product candidates;
- seek to discover and develop additional product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;

- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish sales, marketing and distribution capabilities and scale up and validate external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, scientific and management personnel; and
- expand our operational, financial and management systems and personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase substantially if:

- we are required by the United States Food and Drug Administration, or FDA, or the European Medicine Agency, or EMA, to perform studies in addition to those currently expected; or
- if there are any delays in enrollment of patients in, or completing our clinical trials or the development of any product candidates that we may develop.

Our ability to become and remain profitable depends on our ability to generate revenue. Subject to the effectiveness of the License Agreement with Roche, we do not expect to generate significant revenue unless and until we obtain marketing approval for, and commercialize, EBI-031. This would require us to be successful in a range of challenging activities, including:

- initiating and completing clinical development of EBI-031 in patients with DME, uveitis, or other indications;
- subject to obtaining favorable results from clinical trials, applying for and obtaining marketing approvals for EBI-031;
- establishing sales, marketing and distribution capabilities, either ourselves or through collaboration or other arrangements with third parties, to effectively market and sell EBI-031;
- achieving an adequate level of market acceptance of EBI-031;
- protecting our rights to our intellectual property portfolio related to EBI-031; and
- ensuring the manufacture of commercial quantities of EBI-031.

We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even 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 depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We are devoting substantial financial resources to our ongoing and planned activities including functions associated with operating as a public company. We also may devote additional financial resources to conducting research and development, if we determine to proceed into clinical development, initiating clinical trials of, and seeking regulatory approval for, our product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we would need to devote substantial financial resources to commercialization efforts, including product manufacturing, marketing, sales and distribution. 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 could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

- effectiveness of the License Agreement with Roche;
- the outcome and timing of our review of a range of strategic alternatives with the goal of maximizing stockholder value;

- the scope, progress, results and costs of preclinical development, laboratory testing and, if we determine to proceed into clinical development, clinical trials of our preclinical product candidates;
- our ability to establish collaborations on favorable terms, if at all, particularly manufacturing, marketing and distribution arrangements for our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the extent to which we in-license or acquire rights to other products, product candidates or technologies.

We believe the our cash and cash equivalents of $8.5 million as of June 30, 2016, together with the aggregate upfront and initial milestone payments of approximately $30 million that will be due and payable within 30 days after effectiveness of the License Agreement with Roche, will be sufficient to fund our current operating plan into 2017. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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 regulatory approval and achieve product sales. Our commercial revenues, if any, will be derived from sales of any products that we successfully develop, none of which we expect to be commercially available for many years, if at all. In addition, if approved, any product candidate that we develop or any product that we in-license may not achieve commercial success. Accordingly, we will need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K.

Our report from our independent registered public accounting firm for the year ended December 31, 2015 includes an explanatory paragraph stating that our losses from operations and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable 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 equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements and marketing and distribution arrangements. We do not have any committed external source of funds other than the amounts payable under the License Agreement with Roche, subject to the effectiveness thereof. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as holders of our common stock. For example, in December 2014, we issued and sold in a private placement an aggregate of 1,743,680 shares of our common stock, plus warrants to purchase a total of 871,840 additional shares of common stock, which resulted in dilution to our existing stockholders. Additionally, since April 2015, we have issued and sold 1,446,781 shares of our common stock in "at the market" offerings, which resulted in dilution to our existing stockholders.

Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through government or other third-party funding, collaborations, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

Our limited 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 incorporated and commenced active operations in early 2008, and our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. All of our product candidates which we are currently pursuing are still in preclinical development. We have not yet demonstrated our ability to successfully complete clinical development of any product candidate, obtain marketing approvals, manufacture at commercial scale, or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. 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 at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to 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 are considering alternatives to our current business strategy that could significantly impact our future operations and financial position.

We are in the process of reviewing a range of strategic alternatives that could result in potential changes to our current business strategy and future operations. As part of this process, we are reviewing alternatives with the goal of maximizing stockholder value. Most of our research and development activities are on hold pending the outcome of this strategic review process as we seek to manage our cash position. As such, our business efforts are currently devoted primarily to our review of strategic alternatives. Potential strategic alternatives that we may continue to explore and evaluate during the ongoing review process include, among others, the sale of the Company, a strategic partnership or a business combination with one or more parties or the licensing, sale or divestiture of some of our assets or proprietary technologies that are not related to the License Agreement. We cannot provide any commitment regarding precisely when or if this strategic review process will result in any type of additional transaction and no assurance can be given that we will determine to pursue a potential sale, strategic partnership, business combination or other arrangement. If we determine to pursue an alternative strategy or engage in a strategic transaction, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or projected by our management. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our existing business strategy.

Risks Related to the Discovery and Development of Our Product Candidates

We depend heavily on the success of EBI-031, our most advanced product candidate, which is still in preclinical development. If we or Roche are unable to successfully commence and complete our planned clinical program and obtain marketing approvals for EBI-031, or experience significant delays in doing so, or if after obtaining marketing approvals, we or Roche fail to commercialize EBI-031, our business will be materially harmed.

We are in the early stages of development of EBI-031. We submitted an IND for EBI-031 for the treatment of DME and uveitis in June 2016, which received IND Clearance from the FDA on July 7, 2016, and enables initiation of clinical development of this product candidate.

The success of EBI-031 will depend on several factors, including the following:

- commencing clinical development of EBI-031;
- completing clinical development of EBI-031 in patients with DME, uveitis or other indications;
- manufacturing commercial quantities of EBI-031 and receiving regulatory approval of manufacturing processes and facilities from applicable regulatory authorities;

- subject to obtaining favorable results from clinical trials, applying for and obtaining marketing approvals for EBI-031;
- effectively marketing and selling EBI-031;
- acceptance of EBI-031, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, including the existing standard of care;
- maintaining a continued acceptable safety profile of EBI-031 following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting rights in our intellectual property portfolio related to EBI-031.

Successful development of EBI-031 for use in broader patient populations and the ability of Eleven or Roche, if EBI-031 is approved, to broaden the label will depend on similar factors. If we or Roche 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 EBI-031, which would materially harm our business.

If clinical trials of any product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of any product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans . 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, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For example, in May 2015, we announced top-line results from our Phase 3 clinical trial of our product candidate isunakinra in patients with moderate to severe dry eye disease. In this trial, there was no statistically significant difference between the isunakinra treated group and the vehicle control group on the co-primary endpoints. In addition, there were no statistically significant differences between the isunakinra treated group and the vehicle treated group on any secondary endpoints. Additionally, in January 2016, we announced top-line results from our Phase 3 clinical trial of isunakinra in patients with severe allergic conjunctivitis. In this trial, there was no statistically significant difference between the isunakinra treated group and the vehicle control group on the primary endpoint of ocular itching or on any secondary endpoints.

Our prior clinical development efforts of isunakinra for the treatment of patients with dry eye disease and allergic conjunctivitis were not successful. We expended significant resources to pursue development of this product candidate and may in the future expend our limited resources to pursue development of a particular product candidate or indication and fail to capitalize on product candidates or indications that have a greater likelihood of clinical success or commercial potential.

We previously invested a significant portion of our efforts and financial resources in the development of isunakinra for the treatment of patients with dry eye disease and allergic conjunctivitis. Notwithstanding this significant investment, based on the results from our completed Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, we do not plan to pursue further development of isunakinra.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. 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 likelihood of clinical success or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. In addition, 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.

If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

We 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 that we may develop, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants 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 or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

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

- be delayed in obtaining marketing approval for our product candidates;
- 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;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

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 may not be able to initiate or continue clinical trials for our product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States.

Patient enrollment is affected by a number of factors, including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- any ongoing clinical trials conducted by competitors for the same indication;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of any product candidates that we may develop, we may need to abandon or limit our development of such product candidates.

If any of our product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow 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. We have no clinical safety data on human exposure to EBI-031 or any of our other preclinical product candidates. Many compounds that initially showed promise in clinical or early stage testing for treating ophthalmic disease have later been found to cause side effects that prevented further development of the compound.

We may not be successful in our efforts to use our AMP-Rx platform to build a pipeline of product candidates.

A key element of our strategy has been to use our proprietary AMP-Rx platform to rationally design, engineer and generate a pipeline of novel protein therapies and progress these therapies through clinical development for the treatment of a variety of ophthalmic diseases. Our research and development efforts to date have resulted in a pipeline of additional product candidates directed at the treatment of ophthalmic diseases. All of the product candidates which we are currently pursuing are in early preclinical research and have not been tested in humans. These and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our technological approach, we will not be able to obtain product revenues in future periods.

Risks Related to the Commercialization of Our Product Candidates

Even if any product candidate that we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity may be smaller than we estimate.

If any product candidate that we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Current treatments that are used for DME and uveitis include blockers of a protein called vascular endothelial growth factor, or VEGF, and low cost, off-label use of corticosteroids. These treatments are well established in the medical community, and doctors may continue to rely on these treatments rather than our product candidates, if and when they are approved for marketing by the FDA. As a result, healthcare professionals and third-party payors may choose to rely on such products rather than our product candidates.

The degree of market acceptance of any product candidate that we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments, including the existing standard of care;

- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. If the actual market for our product candidates is smaller than we expect, our product revenue or license revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing any product candidates that we may develop 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 therapeutic products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties.

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

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may enter into arrangements with third parties to perform sales, marketing and distribution services in markets outside the United States. We may also enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States or if we determine that such third-party arrangements are otherwise beneficial. Our product revenues and our profitability, if any, under any such third-party sales, marketing or distribution arrangements are likely to be lower than if we were to market, sell and distribute any product candidates that we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates that we may develop.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. 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 are developing our product candidates. 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.

The current standard of care for DME includes anti-VEGF therapies and corticosteroids. Some patients with DME are effectively treated by the current standard of care therapies. Approved anti-VEGF therapies for treating DME include Lucentis (ranibizumab) and Eylea® (aflibercept). Off-label use of Avastin (bevacizumab) is also seen in DME. Approved corticosteroid therapies include Ozurdex (dexamethasone implant) and Iluvien (fluocinolone implant). Laser photocoagulation was historically the standard of care for treating DME, in particular for a subcategory of DME called clinically significant macular edema, and is still used to treat some DME patients. However, anti-VEGF therapy has been proven in clinical studies to have superior efficacy over laser photocoagulation.

New areas that are being investigated for pharmacologic treatment of DME include targets and pathways such as mammalian target of rapamycin, or mTOR, tie-2 activators, integrin antagonists, synthetic derivative of testosterone, intercellular adhesion molecule-1, or ICAM-1, matrix metalloproteinases, or MMPs, receptor for advance glycation products, or RAGE, renin-angiotensin system, bradykinin pathway inhibitors and others.

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 product candidates that we may develop. 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.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payors, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If any product candidate that we may develop achieves marketing approval, we expect that it will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidate that we may develop, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize any product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans 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. Coverage and

reimbursement may not be available for any product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement 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 coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop would compromise our ability to generate revenues and become profitable.

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

There can be no assurance that our product candidates or any products that we may in-license, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that they will be considered cost-effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our strategy of obtaining rights to product candidates and approved products for the treatment of a range of ophthalmic diseases through in-licenses and acquisitions may not be successful.

We may expand our product pipeline through opportunistically in-licensing or acquiring the rights to other products, product candidates or technologies for the treatment of ophthalmic diseases. The future growth of our business may depend in part on our ability to in-license or acquire the rights to approved products, additional product candidates or technologies. However, we may be unable to in-license or acquire the rights to any such products, product candidates or technologies from third parties. The in-licensing and acquisition of pharmaceutical products is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire products, product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to in-license or acquire the rights to the relevant product, product candidate or technology on terms that would allow us to make an appropriate return on our investment. Furthermore, we may be unable to identify suitable products, product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable products, product candidates or technologies, our ability to pursue this element of our strategy could be impaired.

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

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

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

We currently hold $5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $5.0 million, which may not be adequate to cover all liabilities that we may incur. We would need to increase our insurance coverage if we expand our clinical development activities beyond historical levels. We would need to further increase our insurance coverage if we commence commercialization of any product candidate that receives marketing approval. 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.

Risks Related to Our Dependence on Third Parties

The successful commercialization and continued development of EBI-031 depends substantially on the License Agreement with Roche. If Roche is unable or unwilling to commercialize or further develop EBI-031, or experiences significant delays in doing so, our business will be materially harmed.

On June 10, 2016, we entered into the License Agreement with Roche for the development and commercialization of EBI-031. Prior to this agreement, we did not have a history of working with Roche. Subject to effectiveness of the License Agreement, the agreement provides for milestone payments to us based on the achievement of specified development, regulatory and commercial milestones, and provides us with royalty-based revenue if EBI-031 is successfully commercialized. We cannot predict the success of the License Agreement.

Subject to effectiveness of the License Agreement, we will be substantially dependent on Roche to develop and commercialize EBI-031. Under the License Agreement, Roche has significant control over the conduct and timing of development and commercialization efforts with respect to EBI-031. We have little control over the amount, timing and quality of resources that Roche devotes to the development or commercialization of EBI-031. If Roche fails to devote sufficient financial and other resources to the future development or commercialization of EBI-031, the development and commercialization of EBI-031 would be delayed or could fail. This would result in a delay in our receiving milestone payments or royal ties at all.

We may enter into collaborations or license agreements with third parties for the development or commercialization of our product candidates. If our collaborations or licenses are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators or licensees for development and commercialization of our product candidates. Our likely collaborators or licensees for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement, other than the License Agreement with Roche. Our ability to generate revenues from these arrangements will depend on our collaborators' or licensee's abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations and licenses involving our product candidates, including the License Agreement with Roche, pose a number of risks, including the following:

- collaborators or licensees have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations or licenses;
- collaborators or licensees may not perform their obligations as expected;
- collaborators or licensees may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' or licensees' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators or licensees 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 or licensees could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators or licensees believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered under the collaboration or license with us may be viewed by our collaborators or licensees as competitive with their own product candidates or products, which may cause collaborators or licensees to cease to devote resources to the commercialization of our product candidates;
- a collaborator or licensee with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators or licensees, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators or licensees may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators or licensees may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations or licenses may be terminated for the convenience of the collaborator or licensee and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements and licenses may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations or licenses that we enter into, do not result in the successful development and commercialization of products or if one of our collaborators or licensees terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration or license. For example, we were collaborating with ThromboGenics, N.V., or ThromboGenics, under a collaboration and license agreement, to identify protein or peptide therapeutics that directly modulate any of a specified set of targets in a novel pathway in retinal disease. On August 1, 2016, we received notice from ThromboGenics of its termination, effective October 31, 2016, of the collaboration and license agreement. No collaboration products have been identified under the agreement. We do not expect to receive payment for any future potential milestones or royalties under the ThromboGenics collaboration and license agreement. All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report on Form 10-Q also apply to the activities of our collaborators and licensees.

Additionally, subject to its contractual obligations to us, if a collaborator or licensee of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators or licensees terminates its agreement with us, we may find it more difficult to attract new collaborators or licensees and our perception in the business and financial communities could be harmed.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of therapeutic products. 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 for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

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

We have relied on third parties, such as CROs, to conduct our clinical trials of isunakinra and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct any clinical trials of our product candidates. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

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 specified 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 our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We expect to contract with third parties for the manufacture of our product candidates for clinical trials and would expect to continue to do so in connection with the commercialization of any product candidates that receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We rely, and expect to continue to rely, on third parties to manufacture preclinical and clinical supplies of our product candidates that we may develop and commercial supplies of products if and when any of our product candidates receives marketing approval. Our current and anticipated future dependence upon others for the manufacture of any product candidate or product that we develop may adversely affect our future profit margins and our ability to commercialize any

products that receive marketing approval on a timely and competitive basis. In addition, any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

The FDA maintains strict requirements governing the manufacturing process for biologics. When a manufacturer seeks to modify or make even seemingly minor changes to that process, the FDA may require the applicant to conduct a comparability study that evaluates the potential differences in the product resulting from the change in the manufacturing process. The agency has issued several guidances on this point. In connection with our application for a license to market our product candidates in the United States, we may be required to conduct a comparability study if the product we intend to market is supplied by a manufacturer different from the one who supplied the product evaluated in our clinical studies. Delays in designing and completing this study to the satisfaction of the FDA could delay or preclude our development and commercialization plans and thereby limit our revenues and growth.

Reliance on third-party manufacturers entails additional risks, including:

- any product candidates that we may develop may compete with other product candidates and products for access to a limited number of suitable manufacturing facilities that operate under current good manufacturing practices, or cGMP, regulations;
- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

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 clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. 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 know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents

or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned or licensed patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional preclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith 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.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

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

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

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. The risks of being involved in such litigation and proceedings may increase as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may not be aware of all such intellectual property rights potentially relating to our product candidates and their uses. Thus, we do not know with certainty that EBI-031 or any other product candidate, or our commercialization thereof, does not and will not infringe or otherwise violate any third party's intellectual property.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are party to a number of license agreements and a collaboration agreement that impose, and, for a variety of purposes, we will likely enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under certain of our existing licensing agreements, we are obligated to pay royalties or make specified milestone payments on net product sales of product candidates or related technologies to the extent they are covered by the agreement. We also are obligated under certain of our existing license agreements to pay maintenance and other fees. We also have diligence and development obligations under certain of those agreements that we are required to satisfy. If we fail to comply with our obligations under current or future license and collaboration agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could diminish the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees 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 do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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 technical and management 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise 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, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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, we would have no right to prevent them, or those to whom they communicate it, 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, our competitive position would be harmed.

Risks Related to Regulatory and Marketing Approval of Our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain required regulatory approvals, or there are delays in obtaining approvals, we will not be able to commercialize any product candidate that we may develop, and our ability to generate revenue will be materially impaired. The marketing approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any licensees or collaborators, will obtain marketing approval to commercialize any product candidate.

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. The failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. The activities associated with the development and commercialization of our product candidates, including 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 agencies in the United States and by the EMA and similar regulatory authorities outside the United States. 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.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety, purity and potency. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, EMA or other regulatory authorities may determine that any product candidate that we may develop is not safe, effective or pure, is only moderately effective or has undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Moreover, 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 regulatory 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.

The different requirements of the EMA compared with the FDA may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post approval limitations or restrictions. If we experience delays in obtaining regulatory approvals, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

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 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 EMA or the FDA 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 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.

Our product candidates for which we intend to seek approval as biological products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, abbreviated pathways for approval of biosimilar and interchangeable biological products were created. The BPCIA establishes legal authority for the FDA to review and approve biosimilars for marketing, as well as biosimilars that have been designated as “interchangeable” with a previously approved biologic, or reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a full BLA. This period of non-patent exclusivity runs concurrently with, but is independent of, periods of patent protection for the reference product.

We believe that any of our product candidates approved as a biological product under a full BLA should qualify for a 12-year period of exclusivity. However:

- the United States Congress could amend the BPCIA to significantly shorten this exclusivity period as has been previously proposed; and
- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version.

The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could compromise the future commercial prospects for our biological products. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing at both the federal and state levels of government.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad, and any approval we are granted for our product candidates in the United States would not assure approval of product candidates in foreign jurisdictions.

In order to market and sell any product candidate that we may develop in the European Union and many other jurisdictions, we or our third-party licensees or 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 sold 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 products in any market.

Even if we, or our third-party licensees or collaborators, obtain marketing approvals for our product candidates, the terms of those approvals, ongoing regulations and post-marketing restrictions may limit how we, or they, manufacture and market our products, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators we may have in the future, must therefore comply with requirements concerning advertising and promotion for any of our products for which we or they obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if any product candidate that we may develop receives marketing approval, the accompanying label may limit the approved use of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping, and potentially costly post-marketing studies or other clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our 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 are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval will be subject to a strict enforcement of post-marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

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 product, will be subject to continual requirements of and review by the FDA and other federal and state regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA and other federal and state agencies, including the Department of Justice, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in

accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. Violations of such requirements may lead to investigations alleging violations of the FDCA and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any 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 any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which 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, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation

to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals, with data collection beginning in August 2013;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, 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; state and foreign 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 or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of 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 other product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any 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 collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our product candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription products and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal 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 of applicable brand products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient products to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- 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 certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report product samples that manufacturers and distributors provide to physicians;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a new Independent Payment Advisory Board, or IPAB, which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models.

Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislation, will continue until 2025. In addition, 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 regulatory approval is obtained.

We expect that the PPACA, 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 in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

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

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or 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.

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. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product 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 civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

If we or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, provide accurate information to the FDA or comparable non-U.S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards 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 and results of operations, including the imposition of significant fines or other sanctions.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical and business development expertise of Abbie Celniker, Ph.D., our President and Chief Executive Officer, Karen L. Tubridy, our Chief Development Officer, Michael H. Goldstein, M.D., our Chief Medical Officer, and John J. McCabe, our Chief Financial Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. For example, in January 2016, Eric Furfine, Ph. D., notified us of his resignation as our Chief Scientific Officer. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

If we expand our development and regulatory capabilities or implement sales, marketing and distribution capabilities, we may encounter difficulties in managing our growth, which could disrupt our operations.

To manage 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 growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical and commercialization activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our product research, development and commercialization efforts could be delayed.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

As of July 31, 2016 , our current executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially owned shares representing approximately 64.3% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

Our shares of common stock began trading on The NASDAQ Global Market on February 6, 2014. 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 price of our common stock has been volatile and may fluctuate in the future, which could result in substantial losses for our stockholders.

The trading price of our common stock has and may continue to fluctuate significantly. During the period from January 4, 2016 to July 31, 2016 , the closing sales price of our common stock ranged from a high of $4.54 per share to a low of $0.25 per share. Our stock price experienced significant volatility in May 2015 after we announced that we failed to meet either of the two co-primary endpoints in our Phase 3 clinical trial of isunakinra in patients with moderate to severe dry eye disease and in January 2016 after we announced that we failed to meet the primary endpoint in our Phase 3 clinical trial of isunakinra in patients with allergic conjunctivitis. Furthermore, the stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular

companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased their shares. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of EBI-031 or any other product candidate that we may develop;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional products, product candidates or technologies for the treatment of ophthalmic diseases, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class action litigation has often been instituted against that company. We also may face securities class action litigation if we cannot obtain regulatory approvals for or if we otherwise fail to commercialize EBI-031. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

If we fail to continue to meet all applicable continued listing requirements of The NASDAQ Global Market and NASDAQ determines to delist our common stock, the market liquidity and market price of our common stock could decline.

Our common stock is listed on The NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other continued listing requirements. On March 3, 2016, we received the following notifications from the NASDAQ Listings Qualifications Department:

- For the prior 30 consecutive business days, the bid price of our common stock on The NASDAQ Global Market closed below the minimum $1.00 per share required for continued inclusion under NASDAQ Marketplace Rule 5810(c)(3)(A), or the Minimum Bid Price Rule.
- For the prior 30 consecutive business days, our stockholders’ equity did not comply with the minimum stockholders’ equity requirement of $5,000,000 for continued listing on The NASDAQ Global Market pursuant to NASDAQ Marketplace Rule 5810(c)(3)(D), or the Minimum Market Value Rule.

On May 3, 2016, we received notification from the NASDAQ Listing Qualifications Department that we had regained compliance with the Minimum Market Value Rule, and on May 31, 2016, we received notification from the NASDAQ Listing Qualifications Department that we had regained compliance with the Minimum Bid Price Rule. However, we may in the future fail to satisfy these or other continued listing standards of the NASDAQ Global Market. In the event that we are unable to satisfy the continued listing standards of the NASDAQ Global Market, our common stock may be delisted from that market. Any delisting of our common stock from the NASDAQ Global Market could adversely affect our ability to attract new investors, decrease the liquidity of our outstanding shares of common stock, reduce our flexibility to raise additional capital, reduce the price at which our common stock trades and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholders. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our securities at all. For these reasons and others, delisting could adversely affect the price of our common stock and financial condition and business prospects.

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

As of December 31, 2015, we had federal net operating loss, or NOL, carryforwards of $120.0 million, state NOL carryforwards of $118.2 million and federal and state research and development tax credit carryforwards of $1.7 million and $1.2 million, respectively. These federal and state NOL carryforwards and federal and state tax credit carryforwards expire at various dates beginning in 2029 through 2035, if not utilized. Utilization of these NOL and tax credit carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and comparable provisions of state, local and foreign tax laws due to changes in ownership of our company that have occurred previously or that could occur in the future. Under Section 382 of the Code and comparable provisions of state, local and foreign tax laws, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes, such as research and development tax credits, to reduce its post-change income may be limited. We have determined that it is more likely than not that our net operating and tax credit amounts disclosed are subject to a material limitation under Section 382 resulting in available federal net operating loss, or NOL, carryforwards of $119.2 million, state NOL carryforwards of $117.4 million and federal and state research and development credit carryforwards of $1.6 million and $1.2 million, respectively, available to reduce future taxable income. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we generate taxable income, our ability to use our pre-change NOL and tax credits carryforwards to reduce U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liability to us.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of July 31, 2016 , we had outstanding 20,058,298 shares of common stock. Of these shares, 7,729,634 shares are restricted securities under Rule 144 under the Securities Act. Any of our remaining shares that are not restricted securities under Rule 144 under the Securities Act may be resold in the public market without restriction unless purchased by our affiliates.

Moreover, holders of an aggregate of 8,020,538 shares of our common stock have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. On April 9, 2014, we filed a registration statement registering all shares of common stock that we may issue under our equity compensation plans. As of July 31, 2016 , we had outstanding options to purchase an aggregate of approximately 2,116,944 shares of our common stock, of which options to purchase approximately 1,028,160 shares were vested. These shares can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in the 2015 10-K. In particular, the 2015 10-K did not include all of the executive compensation related information that would be required if we were not an emerging growth company. We expect to continue, in our public reporting, to take advantage of some or all of the reporting exemptions available to emerging growth companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If

some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards . This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to delay such adoption of new or revised accounting standards, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

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

As a public company, and particularly after we are no longer an emerging growth company, we will 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 Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

For as long as we remain an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies as described in the preceding risk factor. We may remain an emerging growth company until the end of the 2019 fiscal year, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an emerging growth company if we issue more than $1 billion of non-convertible debt over a three-year period.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain.

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

We did not sell or issue any equity securities that were not registered under the Securities Act during the period covered by this Quarterly Report on Form 10-Q.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index immediately preceding such exhibits, and are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

ELEVEN BIOTHERAPEUTICS, INC.

By: /s/ John J. McCabe

John J. McCabe

Chief Financial Officer (Principal Financial and Accounting Officer)

August 12, 2016

EXHIBIT INDEX

Exhibit No.	Description
10.1*†	License Agreement, dated as of June 10, 2016, by and among Eleven Biotherapeutics, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.
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.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

Exhibit 10.1

Confidential

License Agreement

This Agreement, dated as of June 10, 2016, is entered into by and between

F. Hoffmann-La Roche Ltd

with an office and place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland (" **Roche Basel** ")

and

Hoffmann-La Roche Inc.

with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. (" **Roche US** "; Roche Basel and Roche US together referred to as " **Roche** ")

on the one hand

and

Eleven Biotherapeutics, Inc.

with an office and place of business at 215 First Street, Suite 400, Cambridge, Massachusetts 02142, U.S.A. (" **Eleven** ")

on the other hand.

Table of Contents

License Agreement

WHEREAS, Eleven has discovered proprietary IL-6 antagonist monoclonal antibodies, including the compound known as EBI-031 (as defined below), and possesses proprietary intellectual property rights relating thereto; and

WHEREAS, Roche has expertise in the research, development, manufacture and commercialization of pharmaceutical and diagnostic products, and wishes to develop and commercialize such IL-6 antagonist monoclonal antibodies; and

WHEREAS, Eleven is willing to grant to Roche rights to use certain of its intellectual property rights to make, use, offer for sale, sell and import and export Licensed Compounds and Licensed Products in the Territory for use in the Field (as such terms are respectively defined below), as contemplated herein.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

1. Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Affiliate

The term “Affiliate” shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with the Party or specified entity in question. As used in this definition of “Affiliate,” the term “control” shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, neither Chugai Pharmaceutical Co., Ltd, a Japanese corporation (“ **Chugai** ”) or its subsidiaries (if any) nor Foundation Medicine, Inc., a Delaware corporation (“ **FMI** ”) or its subsidiaries (if any) shall be deemed as Affiliates of Roche unless Roche provides written notice to Eleven of its desire to include Chugai, FMI or their respective subsidiaries (as applicable) as Affiliate(s) of Roche.

1.2 Agreement

The term “Agreement” shall mean this document, including any and all appendices and amendments to it, as may be amended from time to time in accordance with the provisions of this Agreement.

1.3 Agreement Term
The term "Agreement Term" shall mean the period of time commencing on the Signature Date and ending on the earlier of the Expiration Date or the effective date of termination of the Agreement if the Agreement is terminated prior to the Expiration Date as provided in Article 18.

1.4 Alternative Transaction
The term "Alternative Transaction" shall mean any exclusive outbound license of, exclusive collaboration regarding, or sale, transfer or other disposition, of a material portion of Eleven's assets, rights and know-how in Eleven's IL-6 program, including EBI-031, whether by agreement, equity purchase, asset purchase, merger, business combination, restructuring or otherwise, it being understood and agreed that the following shall not constitute an "Alternative Transaction": (i) a Carve-Out Transaction, (ii) a financing transaction solely related to the continued financing of the operations of Eleven or (iii) the transactions contemplated by this Agreement.

1.5 Applicable Law
The term "Applicable Law" shall mean any law, statute, ordinance, code, rule or regulation that has been enacted by a government authority (including without limitation, any Regulatory Authority) and is in force as of the Signature Date or comes into force during the Agreement Term, in each case to the extent that the same is applicable to the performance by the Parties of their respective obligations under this Agreement.

1.6 Base Returnable Product
The term "Base Returnable Product" shall mean, with respect to a given Returnable Product, the Returnable Product in its then-existing form at the time of a Roche Activated Termination applicable to such Returnable Product.

1.7 Biosimilar Product
The term "Biosimilar Product" shall mean, with reference to a given Licensed Product in a country, a Product that (i) is not produced, licensed or owned by the Roche Group, (ii) is, according to the relevant Regulatory Authority for the given country or jurisdiction, highly similar with respect to the given Licensed Product, notwithstanding minor differences in clinically inactive components, and with no meaningful differences between the Biosimilar Product and the given Licensed Product in terms of the efficacy, safety, purity and potency of the product and (iii) is approved through an abbreviated regulatory pathway. For countries or jurisdictions where no explicit biosimilar regulations exist, a Biosimilar Product includes any Product that (x) has been deemed to be a biosimilar to the given Licensed Product by a Regulatory Authority in another country or jurisdiction or (y) has the same amino acid sequence as the Compound in such Licensed Product.

1.8 BLA
The term "BLA" shall mean a Biologics License Application, or similar application for marketing approval, of a Product for use in the Field submitted to the FDA, or a foreign equivalent of the FDA.

1.9 Business Day
The term "Business Day" shall mean 9.00am to 5.00pm local time on a day other than a Saturday, Sunday or other day on which commercial banking institutions in New York, New York are authorized or permitted by law to be closed.

1.10 Calendar Quarter
The term "Calendar Quarter" shall mean each period of three (3) consecutive calendar months, ending March 31, June 30, September 30, and December 31.

1.11 Calendar Year
The term "Calendar Year" shall mean the period of time beginning on January 1 and ending December 31, except for the first year of the Agreement Term which shall begin on the Effective Date and end on December 31.

1.12 Carve-Out Transaction
The term "Carve-Out Transaction" means a merger, tender offer, consolidation or other business combination pursuant to which the overall business or assets of Eleven is combined with that of a Third-Party in a transaction (i) that, if to be entered into prior to the Effective Date, will provide for the continued effectiveness of this Agreement and the rights and obligations of the Parties and (ii) that specifically contemplates the exclusion of Eleven's development and commercialization rights with respect to the IL-6 program, including EBI-031.

1.13 Change of Control
The term "Change of Control" shall mean, with respect to Eleven: (i) the acquisition by any Third Party of beneficial ownership of fifty percent (50%) or more of the then-outstanding common shares or voting power of Eleven, other than acquisitions by employee benefit plans sponsored or maintained by Eleven; (ii) the consummation of a business combination involving Eleven,

unless, following such business combination, the stockholders of Eleven immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (50%) of the then outstanding common shares or voting power of the entity resulting from such business combination; or (iii) the sale of all or substantially all of Eleven's assets or business to a Third Party.

1.14 Change of Control Group

The term "Change of Control Group" shall mean the person or entity, or group of related persons or entities, that is the acquirer of, or the successor to, Eleven in connection with a Change of Control of Eleven, together with Affiliates of such persons or entities that are not Affiliates of Eleven immediately prior to the completion of such Change of Control of Eleven.

1.15 Clinical Study

The term “Clinical Study” shall mean a Phase I Study, a Phase II Study or Phase III Study, as applicable.

1.16 Combination Product

The term “Combination Product” shall mean

a) a single pharmaceutical formulation containing as its active ingredients both
   (i) a Compound and
   (ii) one or more other therapeutically or prophylactically active ingredients that are not Compounds (each such therapeutically or prophylactically active ingredients, a “ **Non-Compound Active Agent** ”), or
b) a combination therapy comprised of
   (i) a Compound and
   (ii) one or more other therapeutically or prophylactically active products containing at least one Non-Compound Active Agent but not containing any Compounds,

   priced and sold in a single package containing such multiple products or packaged separately but sold together for a single price,

in each case, including all dosage forms, formulations, presentations, line extensions, and package configurations. All references to Product in this Agreement shall be deemed to include Combination Product; all references to Licensed Product in this Agreement shall be deemed to include Combination Products containing a Licensed Product.

1.17 Commercially Reasonable Efforts

The term “Commercially Reasonable Efforts” shall mean such level of efforts consistent with

(i) with respect to Eleven, the efforts that a company of comparable size and resources to and at the same stage of development as Eleven devotes, and

(ii) with respect to Roche, the efforts that Roche devotes,

at the same stage of development or commercialization (including, as applicable, to the Handling of Patent Rights), as applicable, for its own internally developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life taking into account the existence of other competitive products in the market place or under development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors. It is understood that such product potential may change from time to time based upon changing scientific, business and marketing and return on investment considerations.

However, Roche (and its Affiliates) does not always seek to market its own products in every country or seek to obtain regulatory approval in every country or for every potential indication. As a result, except as expressly set forth in Article 3, the exercise of diligence by Roche is to be determined by judging Roche’s commercially reasonable efforts, taken as a whole.

1.18 Companion Diagnostic

The term “Companion Diagnostic” shall mean any product that is used for predicting or monitoring the response of a human being to treatment with a Product (e.g., device, compound, kit, biomarker or service that contains a component that is used to detect or quantify the presence or amount of an analyte in body or tissue that affects the pathogens of the disease).

1.19 Composition of Matter Claim
The term "Composition of Matter Claim" shall mean a Primary Composition of Matter Claim or a Secondary Composition of Matter Claim.

1.20 Compound
The term “Compound” shall mean any IL-6 antagonist anti-IL-6 monoclonal antibody, either whole or an active fragment thereof, including EBI-031.

1.21 Compulsory Sublicense Compensation
The term “Compulsory Sublicense Compensation” shall mean, for a given Licensed Product and a given country or region in the Territory, the compensation paid by a Roche Group Third Party (in such context, a “ **Compulsory Sublicensee** ”) to any member of the Roche Group (other than such Compulsory Sublicensee) under a sublicense of Eleven Patent Rights granted to the Compulsory Sublicensee by a member of the Roche Group through the order, decree or grant of a governmental authority having competent jurisdiction in such country or region, authorizing such Roche Group Third Party to manufacture, use, sell, offer for sale, import or export such Licensed Product in such country or region (the “ **Compulsory Sublicense** ”).

1.22 Confidential Information
The term “Confidential Information” shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by one Party or any of its Affiliates (each, a “ **Disclosing Party** ”) to the other Party or any of its Affiliates (each a “ **Receiving Party** ”), including, after the Effective Date, any Eleven NDA Information and any Eleven MTA Information. Confidential Information shall not include any information, data or know-how that:

(i) was generally available to the public at the time of disclosure by the Disclosing Party to the Receiving Party, or becomes available to the public after disclosure by the Disclosing Party to the Receiving Party other than through fault (whether by action or inaction) of the Receiving Party or any of its Affiliates under circumstances permitting its use or disclosure,
(ii) can be evidenced by written records to have been already known to the Receiving Party or any of its Affiliates prior to its receipt from the Disclosing Party,
(iii) is obtained by the Receiving Party or any of its Affiliates at any time lawfully from a Third Party under circumstances permitting its use or disclosure,
(iv) is developed independently by the Receiving Party or any of its Affiliates as evidenced by written records other than through knowledge of or reference to the Disclosing Party’s Confidential Information, or
(v) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of the Parties, with each Party being considered the Disclosing Party and the Receiving Party with respect thereto.

1.23 Continuation Election Evaluation Process
The term "Continuation Election Evaluation Process" shall mean the procedure described in Section 18.3.2 that may culminate in Eleven providing Roche with a Continuation Election Notice.

1.24 Continuation Election Notice
The term "Continuation Election Notice" shall mean the notice Eleven provides to Roche under Section 18.3.2 describing (i) Eleven's *bona fide* intentions to continue ongoing development and commercialization of specified Returnable Product(s) and (ii) to the extent applicable, Eleven's preliminary request for Roche's continuation of activities during the termination period or transfer of the data, material and information relating to the Returnable Product(s) in accordance with Section 18.3.2.

1.25 Control
The term "Control" shall mean (as an adjective or as a verb including conjugations and variations such as "Controls" "Controlled" or "Controlling") (i) with respect to Patent Rights or Know-How, the possession by a Party (or another specified entity) of the ability to grant a license or sublicense of such Patent Rights or Know-How without violating the terms of any agreement or arrangement between such Party (or such other specified entity) and any other party and (ii) with respect to proprietary materials, the possession by a Party (or another specified entity) of the ability to supply such proprietary materials to the other Party (or another specified entity) as provided herein without violating the terms of any agreement or arrangement between such supplying Party (or such other specified supplying entity) and any other party.

1.26 Cover
The term "Cover" shall mean (as an adjective or as a verb including conjugations and variations such as "Covered," "Coverage" or "Covering") that the developing, making, using, offering for sale, promoting, selling, exporting or importing of a given compound, formulation or product would Infringe a Valid Claim in the absence of a license under or ownership in the Patent Rights to which such Valid Claim pertains. The determination of whether a compound, formulation, process or product is Covered by a particular Valid Claim shall be made on a country-by-country basis; for clarity, Valid Claims that apply to a given country may be national for such country or may be regional or international where and to the extent applicable to such country.

1.27 Core Compound Patent Rights
The term "Core Compound Patent Rights" shall mean the Core Patent Rights, other than the Patent Right listed in the Appendix 1.30 table headed "IL-6 Antagonist Formulations and Uses Thereof" and patents and patent applications claiming priority from such Patent Right and any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

1.28 Early Returnable Product
The term “Early Returnable Product” shall mean a Returnable Product that has not yet reached an end-of-Phase-2 meeting with the FDA or EMA or the Initiation of the first Phase III Study by the effective date of the termination.

1.29 Effective Date
The term “Effective Date” shall mean the date that is one (1) Business Day following the date on which the Stockholder Voting Proposal shall have been authorized at the Company Meeting, at which a quorum is present, by the Required Company Stockholder Vote; provided that no governmental entity of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any order, stay, decree, judgment or injunction or statute, rule or regulation which has the effect of prohibiting the consummation of the transactions contemplated by this Agreement.

1.30 Eleven Base Patent Rights
The term “Eleven Base Patent Rights” shall mean any and all Patent Rights in the Territory that
(a) are Controlled by Eleven on the Signature Date or
(b) are Controlled by Eleven and claim first priority to an application filed after the Signature Date and claim an invention conceived or reduced to practice before the Signature Date by an employee of Eleven or an individual with an obligation to assign all rights in such invention and related Patent Rights to Eleven,
excluding Excluded Eleven Patent Rights and Third Party Eleven IP. Notwithstanding the foregoing, Eleven Base Patent Rights include the Patent Rights listed or described in Appendix 1.30 (the “ **Core Patent Rights** ”).

1.31 Eleven Cell Line Materials
The term “Eleven Cell Line Materials” shall mean the cell lines and cell banks currently used or held for use by or on behalf of Eleven to manufacture or produce Licensed Compounds.

1.32 Eleven Compounds
The term “Eleven Compounds” shall mean the monoclonal antibodies designated as
(i) EBI-031 (“ **EBI-031** ”),
(ii) EBI-028,
(iii) EBI-029, and
(iv) EBI-030.

The sequences of the Eleven Compounds are set forth in Appendix 1.32.

1.33 Eleven Know-How
The term “Eleven Know-How” shall mean Know-How, other than Third Party Eleven IP, that are necessary or reasonably useful for the research, manufacture, development or commercialization of any Licensed Compound or Licensed Product that Eleven Controls
(i) on the Signature Date or

(ii) during the Agreement Term but prior to a Change of Control (however for clarity, even in the event of a Change of Control, Eleven Know-How includes the Know-How relating to Licensed Compounds and Licensed Products to be transferred to Roche in connection with Articles 4, 5 and 6).

1.34 Eleven Patent Rights

The term "Eleven Patent Rights" shall mean

(a) the Eleven Base Patent Rights and

(b) to the extent not included in Eleven Base Patent Rights, the Patent Rights that Eleven Controls on the period commencing the day after the Signature Date and ending at the end of the Agreement Term; provided, however, that

(i) if Roche has exercised a Buy-Out Option, such period shall end on the second (2nd) anniversary of the Expiration Date, and

(ii) in any event, such period shall end on the occurrence of a Change of Control,

but for such subpart (b), excluding Excluded Eleven Patent Rights and Third Party Eleven IP.

1.35 EU

The term "EU" shall mean the European Union and all its then-current member countries, but in any event includes each of the Major EU Countries, whether or not then a member of the European Union.

1.36 Excluded Eleven Patent Right

The term "Excluded Eleven Patent Right" means a claim in a Patent Right Controlled by Eleven that claims a Non-Compound Active Agent, alone or in combination with other molecular entities, none of which can be Compounds. For clarity, if a claim in a Patent Right Controlled by Eleven lists a molecular entity that could be a Compound, then such Patent Right is not an Excluded Eleven Patent Right.

1.37 Exclusivity Agreement

The term "Exclusivity Agreement" means the Exclusivity Agreement by and between the Parties effective as of March 15, 2016.

1.38 Expert

The term "Expert" shall mean a person with no less than ten (10) years of pharmaceutical industry experience and expertise having occupied at least one senior position within a large pharmaceutical company relating to product commercialization or licensing but excluding any current or former employee or consultant of either Party, either Party's Affiliates or a Sublicensee. Such person shall be fluent in the English language.

1.39 Expiration Date

The term "Expiration Date" shall mean

(a) the date Roche provides timely written notice of exercise of a Buy-out Option, or

(b) if Roche does not provide timely written notice of exercise of a Buy-out Option, then on the date after the First Commercial Sale of any Licensed Product when (i) Roche is not conducting any

Clinical Studies of any Licensed Product under this Agreement and (ii) the Royalty Term has ended in each country in the Territory for each Licensed Product having achieved a First Commercial Sale.

1.40 Extended Roche GLP Tox Study

The term "Extended Roche GLP Tox Study" shall mean, in the case where the FDA requires an FDA-Required GLP Tox Study, a GLP toxicity study conducted by or on behalf of Roche that is designed such that the last dose is administered to subjects more than fifteen (15) weeks after the first dose and is either

(a) an FDA-Required GLP Tox Study or

(b) a GLP toxicity study that (i) is not required by the FDA for IND Clearance but still satisfies the FDA's requirements for IND Clearance and (ii) is not run in parallel with or after an FDA-Required GLP Tox Study designed such that the last dose is administered to subjects fifteen (15) or fewer weeks after the administration of the first dose.

1.41 FDA

The term "FDA" shall mean the Food and Drug Administration of the United States of America.

1.42 FDCA

The term "FDCA" shall mean the Food, Drug and Cosmetics Act.

1.43 Field

The term "Field" shall mean all prophylactic, therapeutic and diagnostic use in all indications in humans or animals.

1.44 Filing

The term "Filing" shall mean the acceptance for substantive review of an application submitted to FDA, as provided in the Public Health Services Act and applicable regulations, or the equivalent application to the equivalent agency in any other country or group of countries, the official approval of which is required before any lawful commercial sale or marketing of a given Licensed Product.

1.45 First Commercial Sale

The term "First Commercial Sale" shall mean, on a Licensed Product-by-Licensed Product and country-by-country basis, the first invoiced sale of such a Licensed Product to a Roche Group Third Party by a member of the Roche Group in such country following the receipt of any Regulatory Approval required for the sale of such Licensed Product, or if no such Regulatory Approval is required, the date of the first invoiced sale of such Licensed Product to a Roche Group Third Party by a member of the Roche Group in such country.

1.46 First Option Period

The term “First Option Period” shall mean the period of time commencing on the day after the Initiation of the first Phase II Study for a Licensed Product and ending on the day before the Initiation of the first Phase III Study for a Licensed Product.

1.47 FujiFilm
The term “FujiFilm” or “Fuji” shall mean FujiFilm Diosynth Biotechologies UK Limited, located at Belasis Avenue, Billingham, TS23 1LH, United Kingdom.

1.48 Handle
The term “Handle” shall mean preparing, filing, prosecuting (including interference and opposition proceedings) and maintaining (including interferences, reissue, re-examination, post-grant reviews, inter-parties reviews, derivation proceedings and opposition proceedings).

1.49 ICD-10
The term “ICD-10” shall mean the Tenth Revision of the International Classifications of Diseases and Related Health Problems, as may be revised or amended from time to time, or a successor classification.

1.50 IFRS
The term “IFRS” shall mean International Financial Reporting Standards.

1.51 IND
The term “IND” shall mean, with respect to a Licensed Product, an investigational new drug application as defined in the FDCA and applicable regulations promulgated by the FDA, the filing of which is necessary to commence clinical testing of such Licensed Product in humans.

1.52 IND Clearance
The term “IND Clearance” shall mean the first IND for any Licensed Product going into effect in accordance with 21 C.F.R. 312.40(b).

1.53 IND Clearance Activities
The term “IND Clearance Activities” shall mean any activities required by the FDA (if any), after submission of the IND for EBI-031 by Eleven, to achieve IND Clearance for EBI-031.

IND Clearance Activities to be conducted by or on behalf of Roche (“ **Roche IND Clearance Activities** ”) are:
(a) new GLP toxicology stud(y)(ies) required by the FDA to achieve IND Clearance for EBI-031 (each an “ **FDA-Required GLP Tox Study** ”),
(b) IND Clearance Activities that the Parties mutually agree should be conducted by Roche; and

(c) on or after September 16, 2016, any IND Clearance Activities that Roche requests to either conduct or take over from Eleven.

IND Clearance Activities to be conducted by or on behalf of Eleven (" **Eleven IND Clearance Activities** ") are all IND Clearance Activities other than Roche IND Clearance Activities.

1.54 Indication
The term "Indication" shall mean a disease (i) for which the given Licensed Product is indicated for treatment (or for which a BLA for such Licensed Product is filed) and (ii) that is described in the Licensed Product label as required by the Regulatory Approval granted by the applicable Regulatory Authority (or which is proposed in the BLA).

To distinguish one Indication from another Indication, the two Indications have to be (i) listed in two different blocks of the ICD-10 (as a way of example, any retinopathy under H35 is in a different block from any retinopathy under block H31, whereas H35.023 and H35.031 belong to the same block) and (ii) developed by Roche under separate pivotal Clinical Studies.

1.55 Infringe
The term "Infringe" shall mean (a) with respect to a claim in an issued patent, that such claim would, in the absence of a license under or ownership of such claim, be infringed by the applicable activity, and (b) with respect to a claim in a patent application, that such claim would, in the absence of a license under or ownership of such claim, be infringed by the applicable activity if such claim were to issue.

1.56 Initiation
The term "Initiation" shall mean, as applicable in this Agreement, the date that a human is first dosed with the given Licensed Product in a Clinical Study approved by the respective Regulatory Authority or otherwise permitted under Applicable Law, or the date that the first animal is dosed with a Licensed Product containing EBI-031 in an Extended Roche GLP Tox Study.

1.57 Inventory
The term "Inventory" shall mean all existing clinical and non-clinical grade drug product, active pharmaceutical ingredient, intermediates and raw materials associated with Licensed Compounds in the Control of Eleven, as well as any other existing materials (such as reference standards and retention samples), drug delivery systems and packaging associated with the manufacture or testing of such Licensed Compounds and Licensed Products containing therein.

1.58 Know-How
The term "Know-How" shall mean data, knowledge and information, including materials, samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical data, assays, platforms, formulations, specifications, quality control testing data, that are necessary or reasonably useful for the research, manufacture, development or commercialization of Products.

1.59 Licensed Compound
The term “Licensed Compound” shall mean
(a) any Eleven Compound or
(b) any other Compound that (i) is Covered by a Core Compound Patent Right in the US or EU or (ii) was Covered by an issued Core Compound Patent Right in the US or EU that has expired less than ten (10) years from the applicable date.

1.60 Licensed Product
The term “Licensed Product” shall mean a Product containing a Licensed Compound.

1.61 Major EU Country
The term “Major EU Country” shall mean any of the following: France, Germany, Italy, Spain and the United Kingdom.

1.62 Modified Returnable Product
The term “Modified Returnable Product” shall mean, with respect to a given Returnable Product, a version of the applicable Base Returnable Product modified by or on behalf of Eleven or any of its Affiliates, licensees or sublicensees after the time of the applicable Roche Activated Termination (but before commercialization of the Returnable Product) in a manner consistent with customary progression of the development of such Returnable Product.

1.63 Net Sales
The term “Net Sales” shall mean, for a Licensed Product in a particular period, the amount calculated by subtracting from the Sales of such Licensed Product for such period described in Section 1.87(i): (i) a lump sum deduction of four percent (4%) of such Sales in lieu of those deductions that are not accounted for on a Licensed Product-by-Licensed Product basis (*e.g.* , freight, postage charges, transportation insurance, packing materials for dispatch of goods, custom duties); (ii) uncollectible amounts accrued during such period with respect to such Sales based on a proportional allocation of the total bad debts accrued during such period and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of such Sales of such Licensed Product for such period; (iii) credit card charges (including processing fees) incurred during such period on such Sales and not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of Sales of such Licensed Product for such period; and (iv) government mandated fees and taxes and other government charges accrued during such period with respect to such Sales not already taken as a gross-to-net deduction in accordance with the then currently used IFRS in the calculation of such Sales of such Licensed Product for such period, including, for example, any fees, taxes or other charges that become due in connection with any healthcare reform, change in government pricing or discounting schemes, or other action of a government or regulatory body, but excluding any taxes on net income of a member of the Roche Group. For clarity, no deductions taken in calculating Sales under Section 1.87 may be taken a second time in calculating Net Sales,

and no deductions under this definition of Net Sales may be taken more than once in calculating Net Sales for a given Licensed Product for a given period.

1.64 Non-Prosecution Claim
The term “Non-Prosecution Claim” means a claim in a Patent Right Controlled by Eleven that, (i) in the absence of a license, would not be Infringed by the use or sale of a Compound; (ii) claims a generic class of compounds, a formulation of a generic class of compounds, or a method of making or using a generic class of compounds, which, in the absence of a license, would be Infringed by the use or sale of a Compound and would be Infringed by the use or sale of a compound other than a Compound; or (iii) in the absence of a license, would be Infringed by the use or sale of a Licensed Product and would be Infringed by the use or sale of a corresponding Compound-Free Product. As used in this definition with respect to a given Licensed Product, the term “ **Compound-Free Product** ” means a product that includes the same therapeutically or prophylactically active ingredients as the Licensed Product with the sole exception being the absence of Licensed Compound(s)). For clarity, the determination of whether a given claim in a Patent Right is a Non-Prosecution Claim shall be made on a patent claim basis.

1.65 Non-Prosecution Patent Right
The term “Non-Prosecution Patent Right” means a Patent Right that includes a Non-Prosecution Claim.

1.66 Party
The term “Party” shall mean Eleven or Roche, as the case may be, and “Parties” shall mean Eleven and Roche collectively.

1.67 Patent Rights
The term “Patent Rights” shall mean all rights under any patent or patent application, in any country of the Territory, including any patents issuing on such patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

1.68 Phase I Study
The term “Phase I Study” shall mean a human clinical trial in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.69 Phase II Study
The term “Phase II Study” shall mean a human clinical trial that includes
(i) a control arm (placebo or standard of care),
(ii) a minimum of one hundred (100) patients per indication (except (x) if the indication is an orphan indication as determined under Applicable Law, in which case there shall be no such minimum, or (y) if the clinical trial is intended to explore multiple indications in the same arm or arms of

such clinical trial, in which case a minimum of one hundred (100) total patients, irrespective of indication, shall apply), and

(iii) a minimum duration of dosing for each patient of five (5) months from the initial dose until the last dose, regardless of how frequently any such patients are dosed,

for which the primary endpoints include a determination of dose ranges or a preliminary determination of efficacy in patients being studied, as described in 21 C.F.R. § 312.21(b) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.70 Phase III Study

The term “Phase III Study” shall mean a human clinical trial that is prospectively designed to, if successful, demonstrate statistically whether a product is safe and effective for use in humans in a manner which, if such trial is successful, would be sufficient, alone or with other Clinical Studies, to seek to obtain regulatory approval to market such product in patients having the disease or condition being studied, as described in 21 C.F.R. § 312.21(c) (FDCA), as amended from time to time, and the foreign equivalent thereof.

1.71 Pre-Commercialized Returnable Product

The term “Pre-Commercialized Returnable Product” shall mean a Returnable Product that has not achieved First Commercial Sale anywhere in the Territory on the effective date of termination.

1.72 Primary Composition of Matter Claim

The term "Primary Composition of Matter Claim" shall mean, for a given Licensed Product in a given country of the Territory, a Valid Claim of an Eleven Patent Right that (i) claims the composition of matter of a Compound included in such Licensed Product and (ii) but for the licenses granted in this Agreement would be Infringed by the use or sale of such Compound as a pharmaceutical agent. For clarity, Valid Claims of an Eleven Patent Right that claim manufacturing processes, product-by-process, formulations or delivery devices shall not be deemed as Primary Composition of Matter Claims, provided that a composition claim from the Core Compound Patent Rights which includes a term such as formulation, preparation, pharmaceutical preparation, or similar terms, such as "a composition of formulation x,...", which without such term would be considered a composition of matter claim, will be considered a Primary Composition of Matter Claim.

1.73 Product

The term “Product” shall mean any product containing a Compound as a pharmaceutically active agent, regardless of their finished forms, delivery methods, formulations or dosages.

1.74 Proprietary Manufacturing IP

The term “Proprietary Manufacturing IP” shall mean cell lines, growth media, culture media or technical development/manufacturing know-how that is Controlled by Roche and in Roche’s good faith judgment contains valuable trade secrets with broader applicability than solely to the Returnable Products, and Roche Patent Rights that claim thereof.

1.75 Qualified Person
The term “Qualified Person” shall mean any person or entity making an unsolicited inquiry, proposal or offer with respect to an Alternative Transaction that Eleven’s Board of Directors determines in good faith (after consultation with outside counsel and its financial advisors) is, or could reasonably be expected to lead to an Alternative Transaction that is, more favorable to Eleven or its stockholders than the transactions contemplated by this Agreement, taking into account all the terms and conditions of such proposal or offer, and that is reasonably capable of being completed on the terms proposed, taking into account all financial, regulatory, legal and other aspects of such proposal or offer.

1.76 Regulatory Approval
The term “Regulatory Approval” shall mean any approvals, registrations or authorizations by Regulatory Authority, necessary for the sale of a Product in the Field in a regulatory jurisdiction in the Territory.

1.77 Regulatory Authority
The term “Regulatory Authority” shall mean any national, supranational (e.g., the European Commission, the Council of the European Union, the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, including the FDA, in each country involved in the granting of Regulatory Approval for the Product.

1.78 Required Company Stockholder Vote
The term “Required Company Stockholder Vote” shall mean the affirmative vote in favor of the Stockholder Voting Proposal by the holders of at least a majority of the outstanding shares of Eleven’s common stock, par value $0.001, on the record date for the meeting of Eleven’s stockholders (the “ **Company Meeting** ”) to consider the Stockholder Voting Proposal.

1.79 Responsibility Transfer Date
The term “Responsibility Transfer Date” shall mean the earlier of
(a) the date of the IND Clearance for a Licensed Product containing EBI-031 or
(b) in the case of on-going Roche IND Clearance Activities, the conclusion of Eleven IND Clearance Activities (with the Parties to work in good faith to agree upon the appropriate date for conclusion of Eleven IND Clearance Activities).

1.80 Returnable Product
The term “Returnable Product” shall mean a Licensed Product subject to a Roche Activated Termination that has advanced at least into Initiation of a Phase I Study by the effective date of such Roche Activated Termination.

1.81 Roche Activated Termination
The term "Roche Activated Termination” shall mean a termination by Eleven for Roche’s material breach under Section 18.2.1 or for development discontinuation under Section 18.2.3 (each an

“ **Involuntary Termination** ”) or by Roche without cause under Section 18.2.2 (a “ **Voluntary Termination** ”).

1.82 Roche Group
The term “Roche Group” shall mean collectively Roche, its Affiliates and its Sublicensees.

1.83 Roche Group Third Party
The term “Roche Group Third Party” shall mean a Third Party other than a member of the Roche Group.

1.84 Roche Know-How
The term “Roche Know-How” shall mean all Know-How that (i) Roche and Roche’s Affiliates Control during the Agreement Term and (ii) would be necessary to develop, manufacture or commercialize a given Base Returnable Product; however subject to Sections 18.3.4.2(c) and Section 18.3.4.3.

1.85 Roche Patent Rights
The term “Roche Patent Rights” shall mean all Patent Rights that (i) Roche and Roche’s Affiliates Control during the Agreement Term and (ii) would be necessary to develop, manufacture, import, offer for sale, use or sell a given Base Returnable Product; however subject to Section 18.3.4.3. For purposes of clarity, the Patent Rights identified in Appendix 1.85 (“ **Excluded Roche Patent Rights** ”) are specifically excluded from the Roche Patent Rights.

1.86 Royalty Term
Subject to Section 9.4, the term “Royalty Term” shall mean, on a country-by-country basis, with respect to a Licensed Product, the period of time commencing on the date of First Commercial Sale of such Licensed Product in such country and ending on the later of the date that is (i) ten (10) years after the date of the First Commercial Sale of such Licensed Product in such country, or (ii) the expiration of the last to expire Composition of Matter Claim Covering such Licensed Product or any Compound in such Licensed Product in such country.

1.87 Sales
The term “Sales” shall mean, for a Licensed Product in a particular period, the sum of (i) and (ii):

(i) the amount stated in the Roche Holding AG “Sales” line of its externally published audited consolidated financial statements with respect to such Licensed Product for such period (excluding sales for resale to any Sublicensees that are not Affiliates of Roche). This amount reflects the gross invoice price at which such Licensed Product was sold or otherwise disposed of (other than for use as clinical supplies or free samples) by Roche and its Affiliates to such Third Parties (excluding sales to any Sublicensees that are not Affiliates of Roche) in such period reduced by gross-to-net deductions, if not previously deducted from such invoiced amount, taken in accordance with the then currently used IFRS.

By way of example, the gross-to-net deductions taken in accordance with IFRS as of the Effective Date include the following:

(a) credits, reserves or allowances granted for (i) damaged, outdated, returned, rejected, withdrawn or recalled Licensed Product, (ii) wastage replacement and short-shipments; (iii) billing errors and (iv) indigent patient and similar programs (*e.g.* , price capitation);

(b) governmental price reductions and government mandated rebates;

(c) chargebacks, including those granted to wholesalers, buying groups and retailers;

(d) customer rebates, including cash sales incentives for prompt payment, cash and volume discounts; and

(e) taxes, duties and any other governmental charges or levies imposed upon or measured by the import, export, use, manufacture or sale of a Licensed Product (excluding income or franchise taxes).

For purposes of clarity, sales by Roche and its Affiliates to any Sublicensee that is not a Roche Affiliate for resale shall be excluded from clause (i) of this definition of “Sales”.

(ii) for Sublicensees that are not Roche Affiliates (and excluding Compulsory Sublicensees), the sales amounts reported to Roche and its Affiliates in accordance with the sublicensee contractual terms and their then-currently used accounting standards. For the purpose of clarity, any such Sublicensee sales as reported to Roche in accordance with Compulsory Sublicense agreements shall be excluded from the sales amount.

For clarity, no deductions taken in calculating Sales under this Section 1.87 may be taken a second time in calculating Net Sales, and no deductions under this definition of Sales may be taken more than once in calculating Net Sales for a given Licensed Product for a given period.

1.88 Secondary Composition of Matter Claim

The term "Secondary Composition of Matter Claim" shall mean, for a given Licensed Product in a given country of the Territory, a Valid Claim of an Eleven Patent Right that (i) claims such Product, (ii) but for the licenses granted in this Agreement would be Infringed by the use or sale of such Product, and (iii) is not a Primary Composition of Matter Claim. For clarity, Valid Claims of an Eleven Patent Right that claim manufacturing processes, product-by-process or delivery devices shall not be deemed as Secondary Composition of Matter Claims.

1.89 Second Option Period

The term “Second Option Period” shall mean the period of time commencing on the day after the Initiation of the first Phase III Study for a Licensed Product and ending on the day before the first Filing of a BLA for a Licensed Product in either the US or anywhere in the EU.

1.90 Signature Date
The term “Signature Date” shall mean the date set forth on the cover page to this Agreement.

1.91 Stockholder Voting Proposal
The term “Stockholder Voting Proposal” shall mean the authorization by Eleven’s stockholders of the transactions contemplated by this Agreement, including the grant of the exclusive licenses provided for under, and on the terms and conditions set forth in, this Agreement.

1.92 Sublicensee
The term “Sublicensee” shall mean an entity to which Roche has licensed rights (through one or multiple tiers), other than through a Compulsory Sublicense, pursuant to this Agreement.

1.93 Symbiosis
The term “Symbiosis” shall mean Symbiosis Pharmaceutical Services Ltd., located at Scio House, Unit 10, Stirling University Innovation Park, Stirling FK9 4NF, Scotland, United Kingdom.

1.94 Territory
The term “Territory” shall mean the world.

1.95 Third Party
The term “Third Party” shall mean a person or entity other than (i) Eleven or any of its Affiliates or (ii) Roche or any of its Affiliates.

1.96 Third Party Eleven IP
The term “Third Party Eleven IP” shall mean the Know-How and Patent Rights licensed to Eleven pursuant to its agreements with Thrombogenics N.V. and Novozymes Biopharma DK A/S.

1.97 US
The term “US” shall mean the United States of America and its territories and possessions.

1.98 US$
The term “US$” shall mean US dollars.

1.99 Valid Claim
The term “Valid Claim” shall mean, as applicable, a claim in any (i) unexpired and issued Patent Right that has not been disclaimed, revoked or held invalid by a final nonappealable decision of a court of competent jurisdiction or government agency; or (ii) pending patent application in any country of the

Territory that (a) in the situation where such pending patent application is being Handled by Eleven, Eleven is using Commercially Reasonable Efforts to Handle such pending patent application and such pending patent application is on file with the applicable patent office and has shown evidence of reasonable progression in such applicable patent office to advance to issuance of a patent, and (b) regardless of whether Eleven or Roche is Handling such pending patent application, has been on file with the applicable patent office for no more than seven (7) years from the earliest date to which the patent application claims its earliest priority, wherein following such date such claim is considered expired until the date (if any) that such a claim is issued or accepted for issuance, upon which it is prospectively reinstated as a Valid Claim.

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

Definition	Section
Accounting Period	10.1
Alliance Director	8.1
Bankruptcy Code	20
Breaching Party	18.2.1
Buy-out Notice	9.4
Buy-out Option	9.4
CEEP Start Date	18.3.2
Chugai	1.1
Company Meeting	1.78
Compound-Free Product	1.64
Compulsory Profit Share Percentage	9.3.8
Compulsory Sublicense	1.21
Compulsory Sublicensee	1.21
Core Patent Rights	1.30
Decision Period	13.4
EBI-031	1.32
Eleven Assigned Patent Rights	13.1.2
Eleven IND Clearance Activities	1.53
Eleven MTA Information	21.10
Eleven NDA Information	21.10
Eleven-Originated Transfer Activities	18.3.4.3
Excluded Roche Patent Rights	1.85
Expert Committee	9.3.3
Extended Roche GLP Tox Study Event	9.2
FDA-Required GLP Tox Study	1.53(a)
First Buy-out Option	9.4
FMI	1.1

Definition	Section
HSR Act	14.1.5
Indemnified Party	15.3
Indemnifying Party	15.3
Initiating Party	13.4
Involuntary Termination	1.81
Minimum Transfer Payment	18.3.4.3
MTA	13.9
NDA	21.10
Non-Breaching Party	18.2.1
Non-Compound Active Agent	1.16
Patent Term Extensions	13.8
Payment Currency	10.3
Peremptory Notice Period	18.2.1
Primary Eleven Patent Rights	13.1.1
Redacted Agreement	17.4
Reference Product Sponsor	13.7
Relative Commercial Value	9.3.3
Representatives	19
Roche IND Clearance Activities	1.53
Roche Indemnitees	15.2
Roche Transfer Activities	18.3.4.3
Samples and PI Information	18.3.4.3
Second Buy-out Option	9.4
Select Non-Prosecution Patent Rights	13.2
Sensitive Information	21.4(c)
Settlement	13.4
SPCs	13.8
Suit Notice	13.4
Voluntary Termination	1.81

2. Grant of License

2.1 Grant of Rights

Effective on the Signature Date, Eleven hereby agrees to grant Roche the right to receive the rights and licenses set forth in Section 2.2 as of the Effective Date.

2.2 License

Effective on the Effective Date, Eleven hereby grants to Roche an exclusive (even as to Eleven) right and license, including the right to sublicense, under Eleven's interest in the Eleven Patent Rights and Eleven Know-How to make, have made, use, have used, register, have registered, sell, have sold, offer for sale, import and export Compounds, Products and Companion Diagnostics in the Field in the Territory.

The exclusivity of the above license is subject to the right of Eleven to conduct such pre-clinical development activities, manufacturing and other obligations (if any) in accordance with this Agreement, including Section 4.1.

2.3 Sublicense

2.3.1 Right to Sublicense to its Affiliates

Roche shall have the right to grant sublicenses to its Affiliates (through multiple tiers), and to Chugai or FMI if Chugai or FMI is not an Affiliate under this Agreement, under its rights granted under Section 2.2 without prior approval of Eleven. If a member of the Roche Group grants such a sublicense, Roche shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the Affiliate (or to Chugai or FMI, as applicable) to the same extent as they apply to Roche for all purposes. Roche assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Affiliate (or on Chugai or FMI, as applicable) and shall itself account to Eleven for all payments due under this Agreement by reason of such sublicense.

2.3.2 Right to Sublicense to Third Parties

Roche and its Affiliates shall have the right to grant written sublicenses to non-Affiliate entities (through multiple tiers) under its rights granted under Section 2.2 without prior approval of Eleven. Roche shall inform Eleven promptly after the signature of an agreement under this Section 2.3.2. Each sublicense shall be consistent in all material respects with the terms and conditions of the Agreement. Roche shall be responsible for the payment of all amounts due hereunder, and for all other obligations of its sublicensees under the Agreement as if such obligations were those of Roche. Eleven shall receive a copy of such agreement with a Third Party which may be redacted to exclude financial terms and confidential information of Roche or the Sublicensee. If Roche grants such a sublicense, Roche shall ensure that all of the applicable terms and conditions of this Agreement shall apply to the Sublicensee to the same extent as they apply to Roche for all purposes. Roche assumes full responsibility for the performance of all obligations and observance of all terms so imposed on such Sublicensee and shall itself account to Eleven for all payments due under this Agreement by reason of such sublicense.

2.3.3 Right to Subcontract

Roche shall have the right to subcontract the work performed under this Agreement without prior approval of Eleven, and Roche is responsible for its subcontractors' compliance with this Agreement.

2.4 Retained Rights

Each Party shall retain all rights under any information, data or know-how (including Know-How), Patent Rights and other intellectual property rights that are owned by or licensed to such Party, except for those rights that are expressly granted to the other Party under this Agreement.

3. Diligence

Roche and Eleven shall use Commercially Reasonable Efforts to perform their respective activities contemplated by Articles 4, 5, 6, 7, 8, 13 or 18 of this Agreement and, subject to Section 13.1.1(a), nothing in Articles 4, 5, 6, 7, 8, 13 or 18 shall imply a higher obligation of diligence imposed on either Party. Specifically, Roche agrees to use Commercially Reasonable Efforts to pursue further development and commercialization of Licensed Products in the Field in the Territory and specifically in the US and anywhere in the EU; and Roche shall be deemed to have used Commercially Reasonable Efforts with respect to such obligation if it develops and commercializes at least one Licensed Product in at least one Indication in the US and anywhere in the EU.

4. Development

4.1 Development for IND Clearance

If the FDA requires IND Clearance Activities, Eleven shall be responsible for Eleven IND Clearance Activities at Eleven's cost as necessary to achieve IND Clearance, and Roche shall be responsible at Roche's cost for Roche IND Clearance Activities as necessary to achieve IND Clearance. Each Party shall notify the other Party of the results of any IND Clearance Activity it conducts promptly after its completion, which, in the case of Roche IND Clearance Activities, such notification shall consist of a status update to Eleven regarding Roche's assessment of the progress towards IND Clearance.

As necessary for Roche to continue development of EBI-031, Eleven shall, for three (3) months after the later of the Effective Date and IND Clearance (except as otherwise specifically set forth in this Agreement), cooperate with Roche and disclose and make available to Roche all data and information in Eleven's possession and Control regarding EBI-031.

4.2 Development Other Than IND Clearance Activities

Roche, at its sole cost and discretion (but subject to Article 3), shall be responsible for all development activities of Licensed Products that are not IND Clearance Activities, except that Eleven shall be responsible at its sole cost for any tissue cross-reactivity studies of EBI-031 that Eleven initiates before IND Clearance if such studies are not IND Clearance Activities.

5. Regulatory

5.1 Responsibility

Eleven shall be responsible at its own expense, in consultation with Roche (which consultation shall not in any way be permitted to adversely affect or delay the achievement of IND Clearance), for all regulatory affairs relating to the EBI-031 Product prior to the Responsibility Transfer Date. Promptly after the Responsibility Transfer Date, Eleven shall transfer sponsorship of such IND to the Roche Affiliate designated by Roche, and the Parties will cooperate to draft and execute the necessary documents required to effect such transfer. If the IND for EBI-031 is transferred to Roche prior to achievement of IND Clearance, Eleven will provide to Roche such assistance as is reasonably required by Roche to achieve IND Clearance.

After the Responsibility Transfer Date, Eleven shall promptly transfer (or cause to be transferred) to Roche or Roche's designee all preclinical and regulatory documentation in Eleven's possession and Control regarding the Licensed Product containing EBI-031, to allow Roche to continue development of Products.

Roche shall thereafter be solely responsible at its own expense for all regulatory affairs related to Licensed Products in the Territory, including the preparation and filing of applications for Regulatory Approval, as well as any or all governmental approvals required to develop, have developed, make, have made, use, have used, manufacture, have manufactured, import, have imported, sell and have sold Licensed Products. Roche shall be responsible for pursuing, compiling and submitting all regulatory filing documentation, and for interacting with regulatory agencies, for all Licensed Products in all countries in the Territory. Roche or its Affiliates shall own and file in their sole discretion (but subject to Article 3) all regulatory filings and Regulatory Approvals for all Licensed Products in all countries of the Territory.

5.2 Disclosure Covenant

Eleven will promptly disclose to Roche, to the extent not already provided, the results of all preclinical testing of any Licensed Product in Eleven's possession and Control as exists on the later of the Effective Date or the date of IND Clearance. Eleven will promptly disclose to Roche during the Agreement Term all information in Eleven's possession and Control concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof in humans with respect to any Licensed Product.

6. Manufacture and Supply of Product

6.1 Product Inventory

Appendix 6.1 is a complete list of the Inventory (other than intermediates, raw materials and in-process research material) and Eleven Cell Line Materials under the Control of Eleven as of the Signature Date.

6.2 Responsibility and Transfer

Eleven shall maintain in full force and effect the CMO agreements with Third Parties listed on Appendix 6.2 for such time as Roche reasonably requires to transition, but in no event shall Eleven be required to maintain such agreements for longer than fifteen (15) months after the Effective Date. In particular, Eleven shall, at Roche's expense, ensure during such period (i) the then-existing Inventory

and Eleven Cell Line Materials are stored as on the Effective Date unless Roche provides a written notice requesting otherwise and (ii) the continuation of on-going testing of EBI-031 and Licensed Product containing EBI-031 under such agreements.

Eleven shall maintain responsibility for payment under Third Party CMO agreements for Eleven IND Clearance Activities. Roche (or Roche's designated Affiliate) shall assume responsibility for payment under such Third Party CMO agreements for (i) Roche IND Clearance Activities, (ii) after the Responsibility Transfer Date, such services as Eleven is required to maintain under this Agreement (unless waived in writing by Roche), and (iii) such additional services as Roche requests. At such time as Roche assumes responsibility for payment, Roche (or Roche's designated Affiliate) shall have authority for directing the activities of the applicable CMOs in Eleven's stead (or through Eleven, as applicable) in accordance with the applicable CMO agreement, and Eleven shall cooperate with Roche to ensure transfer of such authority with the applicable CMOs.

Eleven shall maintain responsibility for the existing inventory of EBI-031 and Licensed Product containing EBI-031 up to the Responsibility Transfer Date; however if so requested by Roche, all or a portion of the Inventory and Eleven Cell Line Materials may be transferred prior to the Responsibility Transfer Date (with Eleven having the right to retain such Inventory and Eleven Cell Line Materials needed for Eleven to meet its Eleven IND Clearance Activities under Section 4.1). After the Responsibility Transfer Date (but for no longer than fifteen (15) months after the Effective Date), Eleven shall, via the Third Party CMO agreements (as previously described) under the direction of Roche in Eleven's stead or through Eleven, as applicable, maintain the remaining then-existing Inventory and Eleven Cell Line Materials until such time as (a) Roche requests and Eleven transfers (or causes to be transferred) such Inventory and Eleven Cell Line Materials to Roche or Roche's designee, or (b) Roche or its Affiliate(s) enters into agreements with the applicable CMOs, or such agreements are assigned to Roche or its Affiliate, so that Roche may, directly or through its Affiliates, through such CMOs or other Third Parties, maintain such Inventory and Eleven Cell Line Materials. For clarity, the maintenance by Eleven of the Inventory and Eleven Cell Line Materials under the CMO agreements after the Responsibility Transfer Date shall be paid for by Roche, however such transfer of the Inventory and Eleven Cell Line Materials to Roche or Roche's designee shall be at Eleven's expense. Once Roche or its Affiliate(s) has in place agreements with the applicable CMOs (or such agreements are assigned to Roche or its Affiliate) or Eleven has transferred (or caused to be transferred) the Inventory and Eleven Cell Line Materials to Roche or Roche's designee in accordance with this Section, but in any event no later than fifteen (15) months after the Effective Date, Eleven shall be free to terminate such Eleven CMO agreements.

In addition, at Roche's reasonable request and expense, Eleven shall, within three (3) months after the later of the Effective Date or the Responsibility Transfer Date, support the transfer of such manufacturing activities and related know-how in Eleven's possession and Control to Roche or Roche's designee, including making available to answer Roche questions Eleven representative(s) with historical knowledge of such CMO activities and contracts.

Roche or Roche's designee shall in all other events be responsible at its own expense for the manufacture and supply of clinical and commercial supplies of the Product.

6.3 GMP Quality Agreements and Auditing

Upon Roche's request, the Parties shall execute a separate GMP quality agreement as Roche deems necessary according to US GMP requirements for the sole purpose of allowing Roche to verify Eleven's ability to perform lot disposition according to US GMP requirements and verifying where applicable that current quality agreements in place with CMOs are acceptable for the existing GMP Inventory and GMP Eleven Cell Line Materials.

To the extent it has not done so, and where necessary according to US GMP requirements, Eleven shall
(a) promptly enter into a GMP quality agreement with Eleven's CMOs (including Eurofins Lancaster Laboratories, Inc.), and
(b) in good faith facilitate a joint GMP audit of such CMOs by Eleven with Roche, in each case at Roche's expense.

7. Commercialization

Roche, at its own expense, shall have sole responsibility and, as between the Parties, but subject to Article 3, decision making authority for the marketing, promotion, sale and distribution of Products in the Territory.

8. Information Exchange and Reports

8.1 Alliance Director

Each Party shall appoint one person to be its point of contact with responsibility for facilitating communication and collaboration between the Parties (each, an " **Alliance Director** "). The Alliance Directors shall attempt to facilitate resolution of potential and pending issues and potential disputes. Each Party may change its Alliance Director on written or email notice to the other Party.

8.2 Updates to Eleven

Prior to the first Licensed Product to achieve First Commercial Sale, Roche shall provide Eleven with an annual summary report of the Roche Group's development activities with respect to Licensed Products. In addition, prior to the first BLA Filing, the Roche Alliance Director shall be available upon Eleven's request to answer questions about the status of the Roche Group's development activities once per each Calendar Quarter (except for such Calendar Quarter that Roche provides Eleven with the annual summary report).

9. Payment

9.1 License Fee

Within thirty (30) days after the Effective Date and receipt of an invoice from Eleven, Roche shall pay to Eleven Seven Million Five Hundred Thousand US Dollars (US$ 7,500,000).

9.2 Event Payments

Roche shall pay up to a total of Two Hundred Sixty-Two Million Five Hundred Thousand US Dollars (US$ 262,500,000) in relation to the achievements of events with respect to Licensed Products. The event payments under this Section 9.2 shall be paid by Roche according to the following schedule of development events.

Event		US Dollars (in millions)
IND Clearance-Related Events	(a) IND Clearance (if IND Clearance is achieved on or before September 15, 2016)	$22.5*
	(b) IND Clearance (if IND Clearance is achieved after September 15, 2016 and no Extended Roche GLP Tox Study)	$20*
	(c) Initiation of the first Extended Roche GLP Tox Study (the " **Extended Roche GLP Tox Study Event** ")	$5*
	(d) IND Clearance (if IND Clearance is achieved after September 15, 2016 and subsequent to completion of an Extended Roche GLP Tox Study)	$15
Initiation of the first Phase II Study		$20
Initiation of the first Phase III Study		$30
BLA Filing in US		$25
BLA Filing anywhere in the EU**		$15
BLA Filing in Japan		$10
First Commercial Sale in US		$40
First Commercial Sale anywhere in the EU**		$25
First Commercial Sale in Japan		$10
BLA Filing for a second Indication in US		$10
BLA Filing for a second Indication anywhere in the EU**		$5
Regulatory Approval in a second Indication in US		$30
Regulatory Approval in a second Indication anywhere in the EU**		$20

Except as otherwise set forth in this Section 9.2, each event payment shall be paid only once, the first time the first Licensed Product reaches the applicable triggering event, regardless of the number of times such events are reached and by how many Licensed Products. To the extent that any of the above triggering events contemplate precursor events (e.g., the first Phase III Study for a Licensed Product commonly follows the first Phase II Study for a Licensed Product), such triggering event, if achieved, shall result in the payment of the contemplated precursor milestone payment if such payment has not yet otherwise been triggered.

For any events first achieved by a Licensed Product containing a Licensed Compound other than EBI-031, Eleven shall receive fifty percent (50%) of the amounts in the above table with no further amount owed for any such event; ***provided*** , however, that if the event first achieved with such Licensed

Compound other than EBI-031 involves a non-ophthalmology indication and the event subsequently-achieved with a Licensed Product containing EBI-031 involves an ophthalmology indication, then Eleven shall receive the remaining fifty percent (50%) of such amounts.

* minus the Exclusivity Fee Payment (as such term is defined in the Exclusivity Agreement) previously paid by Roche. For clarity, only one of the IND Clearance payments in clause (a), (b) or (d) above shall be payable under this Agreement, and the Extended Roche GLP Tox Study Event in clause (c) above shall only apply in conjunction with the IND Clearance event payment associated therewith in clause (d) above.

** Event payments shall be reduced by fifty percent (50%) in the event there is no Eleven Patent Right issued anywhere in the EU containing a Primary Composition of Matter Claim Covering the Licensed Compound in such Licensed Product or the Licensed Product at the time the event is achieved.

The applicable IND Clearance event payment shall be made within thirty (30) days after occurrence of the IND Clearance (of which Roche shall timely notify Eleven if the IND Clearance occurs after the Responsibility Transfer Date) and receipt of an invoice from Eleven. For all other event payments, upon achieving events, Roche shall timely notify Eleven and event payments shall be paid by Roche to Eleven within thirty (30) days from occurrence of the applicable event and receipt of an invoice from Eleven.

9.3 Royalty Payments

9.3.1 Royalty Term

Roche shall pay to Eleven royalties on Net Sales of Licensed Products during the applicable Royalty Terms. Thereafter, the licenses granted to Roche shall be fully paid up, irrevocable and royalty-free.

9.3.2 Royalty Rates

The following royalty rates shall apply to the respective tiers of aggregate Calendar Year Net Sales of a Licensed Product in the Territory, on an incremental basis, as follows:

Tier of Calendar Year Net Sales in billion US$	**Percent (%) of Net Sales of Licensed Products containing EBI-031***
0 – 1	7.5%
> 1 – 2	9%
> 2 – 4	11%
> 4	15%

For example, if Net Sales of a Licensed Product containing EBI-031, for a given Calendar Year, are US$ 3.5 billion, then royalties owed to Eleven on such Net Sales of such Licensed Product for that Calendar Year shall equal US$ three hundred thirty million (US$ 330,000,000) calculated as follows:

[(0.075*1 billion)+(0.09*1 billion)+(0.11*1.5 billion)] = US$330,000,000 royalty payment

* Royalty rates on Licensed Products that do not contain EBI-031 shall be at fifty percent (50%) of the EBI-031 royalty rates.

For the purpose of calculating royalties of a Licensed Product, Calendar Year Net Sales and the royalty rates shall be subject to the following adjustments, as applicable:

9.3.3 Combination Product

If Roche or its Affiliates intend to sell a Combination Product, then the Parties shall meet approximately one (1) year prior to the anticipated First Commercial Sale of such Combination Product in the Territory to negotiate in good faith and agree to an appropriate adjustment to Net Sales to reflect the relative commercial value contributed by the components of the Combination Product (the " **Relative Commercial Value** "). If, after such good faith negotiations not to exceed ninety (90) days, the Parties cannot agree to an appropriate adjustment, the dispute shall be initially referred to the executive officers of the Parties in accordance with Section 21.2.

If the Parties are unable to agree on the Relative Commercial Value, then Roche will select one (1) individual who would qualify as an Expert, Eleven will select (1) individual who would qualify as an Expert, and those two (2) individuals shall select one (1) individual who would qualify as an Expert and who shall be chairman of a committee of the three Experts (the "Expert Committee"), each with a single vote. The Expert Committee will promptly hold a meeting to review the issue under review, at which it will consider memoranda submitted by each Party at least fifteen (15) days before the meeting, as well as reasonable presentations that each Party may present at the meeting. The determination of the Expert Committee as to the issue under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide on issues outside the scope mandated under terms of this Section 9.3.3.

For any Combination Product that includes the active ingredient ranibizumab as its only other active ingredient, the Relative Commercial Value of the Licensed Compound may not be less than fifty percent (50%); however if either Eleven or Roche reasonably believes the Licensed Compound in a Combination Product that includes ranibizumab as its only other active ingredient has a Relative Commercial Value of more than fifty percent (50%) in such Combination Product, then the procedure in this Section 9.3.3 shall apply.

9.3.4 No Primary Composition of Matter Claim

With respect to a given Licensed Product, if in a given country within the Territory there is no Primary Composition of Matter Claim Covering such Licensed Product in such country, then

(a) If, after the ten year anniversary of the First Commercial Sale of such Licensed Product in such country, there is a Secondary Composition of Matter Claim Covering such Licensed Product in such country and a Biosimilar Product has entered the market in such country then no royalty payments shall be due to Eleven for such Licensed Product in such country; otherwise

(b) the royalty payments due to Eleven for such Licensed Product in such country shall be reduced by fifty percent (50%).

9.3.5 Biosimilar Product

(a) If a Product that is a Biosimilar Product to a given Licensed Product enters the market in a given country prior to the end of the Royalty Term and Net Sales of such Licensed Product in such country subsequently decrease for two consecutive Calendar Quarters by more than twenty-five percent (25%) of the level of the Net Sales of such Licensed Product in such country achieved in the Calendar Year immediately prior to such entry divided by four, then the royalty rate owed to Eleven for such Licensed Product shall be reduced by fifty percent (50%) in such country.

(b) If subsequent to such a Biosimilar Product entry, the Net Sales of such Licensed Product in such country decrease by more than fifty percent (50%) of the level of the Net Sales of such Licensed Product in such country achieved in the Calendar Year immediately prior to such entry divided by four, then the royalty rate owed to Eleven in such country for such Licensed Product shall be reduced by seventy-five percent (75%) in such country.

9.3.6 Third Party Payments

Eleven shall be responsible for satisfying the obligations of all existing licenses entered into by Eleven prior to the Effective Date. The Roche Group shall be responsible for and pay or have paid the entire consideration owed to any Roche Group Third Party in relation to Roche Group Third Party intellectual property rights the Roche Group secures after the Effective Date.

(a) The Roche Group shall not have the right to deduct any amounts paid by the Roche Group for any Patent Right that claims (i) any pharmaceutically-active compound other than a Licensed Compound, (ii) any use claims (except those claiming one or more approved Indications for the Licensed Product in the given country) or (iii) any manufacturing claims.

(b) For all other Patent Rights that the Roche Group otherwise would have Infringed by selling the relevant Licensed Product in the relevant country, the Roche Group shall have the right to deduct from royalties otherwise due and payable by the Roche Group to Eleven for such Licensed Product in such country under the Agreement (i) a maximum of fifty percent (50%) of the royalties actually paid by the Roche Group to a Roche Group Third Party with respect to such arrangement except for Patent Rights that claim any delivery device and (i) a maximum of twenty-five percent (25%) of the royalties actually paid by the Roche Group to a Roche Group Third Party with respect to such arrangement for Patent Rights that claim any delivery device. Roche may not otherwise deduct the amounts paid to any such Roche Group Third Party, including any amounts for the development of any Licensed Product.

9.3.7 Maximum Deductions

In no event shall the reductions resulting from Sections 9.3.4(b), 9.3.5 or 9.3.6, in the aggregate, reduce the royalty payments to Eleven for any Licensed Product below fifty percent (50%) of the payments that would otherwise be due for such Licensed Product pursuant to Section 9.3.2 and 9.3.3, or, if Section 9.3.5(b) applies, below twenty-five percent (25%) of the payments that would be otherwise due for such Licensed Product pursuant to Section 9.3.2 and 9.3.3.

9.3.8 Apportionment of Compulsory Sublicensee Consideration

Compulsory Sublicense Compensation received by a member of the Roche Group from a Compulsory Sublicensee during the Royalty Term shall be shared with Eleven on an equivalent profit share

percentage (the " **Compulsory Profit Share Percentage** ") calculated for the respective Calendar Year as follows:

$$1.5 \times \frac{\text{(royalties payable to Eleven for the Licensed Product in the Territory)}}{\text{(Net Sales related to the royalties payable for the Licensed Product in the Territory)}}$$

At the end of the Calendar Year, Roche shall pay to Eleven the Compulsory Sublicense Compensation under a given country or region of the Territory multiplied by the Compulsory Profit Share Percentage. The first time the Roche Group receives Compulsory Sublicense Compensation with respect to a given country and Licensed Product, Roche shall provide in writing (to the extent allowed by Applicable Law) the (i) name of the Licensed Product, country and Compulsory Sublicensee to which such Compulsory Sublicense applies and (ii) the reason for the relevant Compulsory Sublicense. For clarity, any sales or payments by Compulsory Sublicensees under a Compulsory Sublicense shall not be considered as Net Sales and shall not give rise to any royalty payment under Section 9.3.2 of this Agreement.

9.4 Buy-out Options

Roche shall have the right by providing written notice (the " **Buy-out Notice** ") during either the First Option Period (the " **First Buy-out Option** ") or the Second Option Period (the " **Second Buy-out Option** "), to elect to make a one-time payment to Eleven to buy-out Roche's remaining payment obligations under the Agreement with respect to events that had not yet been achieved under Section 9.2 and Sales that had not yet been made under Section 9.3 (the First Buy-out Option and the Second Buy-out Option each being a " **Buy-out Option** "). If Roche elects to make such payment by providing a timely Buy-out Notice and thereafter making the associated payment described in this Section, Roche's exclusive license grant pursuant to Section 2.2 shall become perpetual, irrevocable and fully paid-up.

If Roche elects to make the First Buy-out Option, Roche shall pay Eleven a one-time payment of One Hundred Thirty-Five Million US Dollars (US$ 135,000,000) within thirty (30) days after providing such timely Buy-out Notice to Eleven and receipt by Roche of an invoice in such amount, after which Roche shall have no further payment (under Sections 9.2 and 9.3) or diligence obligations to Eleven under the Agreement (including, for clarity, any milestone payments on events that occur after delivery of the Buy-out Notice, but not prior to delivery of the Buy-out Notice).

If Roche elects to make the Second Buy-out Option, Roche shall pay Eleven a one-time payment of

(i) Two Hundred Sixty-Five Million US Dollars (US$ 265,000,000) in the event a Patent Right containing a Primary Composition of Matter Claim Covering any Licensed Compound or Licensed Product has issued anywhere in the EU, or

(ii) Two Hundred Twenty Million US Dollars (US$ 220,000,000) in the event no Patent Right containing a Primary Composition of Matter Claim Covering any Licensed Compound or Licensed Product has issued anywhere in the EU,

within thirty (30) days after providing such timely Buy-out Notice to Eleven and receipt by Roche of an invoice in such amount, after which Roche shall have no further payment (under Sections 9.2 and 9.3) or diligence obligations to Eleven under the Agreement (including, for clarity, any milestone

payments on events, or royalties on Sales, that occur after delivery of the Buy-out Notice, but not prior to delivery of the Buy-out Notice).

If Roche does not elect to make a Buy-out Option, all remaining payment obligations pursuant to Sections 9.2 and 9.3 shall continue.

9.5 Disclosure of Payments
Each Party acknowledges that the other Party may be obligated to disclose this financial arrangement, including all fees, payments and transfers of value, as may be advisable or required under Applicable Law, including the US Sunshine Act.

10. Accounting and Reporting

10.1 Timing of Payments
Roche shall calculate royalties on Net Sales quarterly as of March 31, June 30, September 30 and December 31 (each being the last day of an " **Accounting Period** ") and shall pay royalties on Net Sales within ninety (90) days after the end of each Accounting Period in which such Net Sales occur.

10.2 Late Payment
Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at two (2) percentage points above the average one-month Euro Interbank Offered Rate (EURIBOR), as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

10.3 Method of Payment
Royalties on Net Sales and all other amounts payable by Roche hereunder shall be paid by Roche in US Dollars (the " **Payment Currency** ") from a US bank account in immediately available funds to account(s) designated by Eleven.

10.4 Currency Conversion
When calculating the Sales of any Licensed Product that occur in currencies other than the Payment Currency, Roche shall convert the amount of such sales into Swiss Francs and then into the Payment Currency using Roche's then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements (at the Effective Date, YTD average rate as reported by Reuters).

10.5 Reporting
With each payment Roche shall provide Eleven in writing for the relevant Calendar Quarter on a Licensed Product-by-Licensed Product basis the following information:

(a) Sales in Swiss Francs;
(b) Net Sales in Swiss Francs;
(c) adjustments made pursuant to Section 9.3.3;
(d) Net Sales in Swiss Francs after adjustments made pursuant to Section 9.3.3 in Swiss Francs;
(e) exchange rate used for the conversion of Net Sales from Swiss Francs to the Payment Currency pursuant to Section 10.4;
(f) Net Sales after adjustments made pursuant to Section 9.3.3 in the Payment Currency;
(g) royalty rate pursuant to Section 9.3.2;
(h) adjustments under Sections 9.3.4 - 9.3.7; and
(i) total royalty payable in the Payment Currency after adjustments made pursuant to Sections 9.3.4 - 9.3.7.

11. Taxes

Eleven shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Eleven under this Agreement, excluding any of the foregoing due on the net income of a member of the Roche Group.

If Applicable Law of any country requires withholding of taxes of any type, levies or other charges with respect to any royalty or other amount payable under this Agreement by Roche to Eleven despite Roche's compliance with Section 10.3, then Roche shall promptly pay such tax, levy or charge for and on behalf of Eleven to the proper governmental authority, and shall promptly furnish Eleven with receipt of payment, in which case Roche shall be entitled to deduct the amount of any such tax, levy or charge actually paid from any royalty or other payment due Eleven. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted, including by providing or filing any relevant certificate or other document.

All royalties and payments due to Eleven under the terms of this Agreement are expressed to be exclusive of value added tax (VAT). If VAT applies the VAT amount will be added to any royalties and payments under this Agreement.

12. Auditing

12.1 Eleven Right to Audit

Roche shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties payable under this Agreement. Such books of accounts shall be kept at their principal place of business. At the expense of Eleven, Eleven shall have the right to engage an internationally recognized independent public accountant reasonably acceptable to Roche to perform, on behalf of Eleven, an audit of such books and records of Roche and its Affiliates and Sublicensees that are deemed necessary by the independent public accountant to report on Net Sales of Licensed Product

for the period or periods requested by Eleven and the correctness of any financial report or payments made under this Agreement.

Upon timely request and at least sixty (60) working days' prior written notice from Eleven, such audit shall be conducted in the countries specifically requested by Eleven, during regular business hours in such a manner as to not unnecessarily interfere with Roche's normal business activities. Such audit shall be limited to results in the three (3) Calendar Years prior to audit notification. Accordingly if Eleven does not request an audit of a given Calendar Year for a given country on or before the third (3 rd) anniversary of the end of such Calendar Year, then Eleven will be deemed to have accepted the royalty payments and reports for such country in such Calendar Year.

Such audit shall not be performed more frequently than once per Calendar Year nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements, shall be treated as Roche's Confidential Information subject to the obligations of this Agreement and need neither be retained more than one (1) year after completion of an audit hereof, if an audit has been requested; nor more than three (3) years from the end of the Calendar Year to which each shall pertain; nor more than one (1) year after the date of termination of this Agreement.

12.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share all draft audit findings with Roche before sharing such findings with Eleven and before the final audit report is issued. The final audit report shall be shared with Roche at the same time it is shared with Eleven.

12.3 Over- or Underpayment

If the audit reveals an overpayment, Eleven shall reimburse Roche for the amount of the overpayment within thirty (30) days. If the audit reveals an underpayment, Roche shall make up such underpayment with the next royalty payment or, if no further royalty payments are owed by Roche, Roche shall reimburse Eleven for the amount of the underpayment within thirty (30) days. Roche shall pay for the audit costs if the underpayment of Roche exceeds five percent (5%) of the aggregate amount of royalty payments owed with regard to the royalty statements subject of the audit. Section 10.2 shall apply to this Section 12.3.

13. Intellectual Property

13.1 Prosecution of Primary Eleven Patent Rights

13.1.1 Prior to Exercising Buy-out Option

Until such time as Roche exercises a Buy-out Option (or after the Second Option Period if Roche fails to timely exercise both Buy-out Options), Roche shall, at its own expense and, at Eleven's request, in consultation with Eleven, Handle all

(i) Core Patent Rights and

(ii) other Eleven Patent Rights (excluding Non-Prosecution Patent Rights) claiming Products or any Compound therein (or any uses thereof) for a Product that has reached at least Initiation of a Phase I Study in development by or on behalf of a member of the Roche Group,

collectively the " **Primary Eleven Patent Rights** ".

During such time,

(a) Roche shall use Commercially Reasonable Efforts to Handle Primary Eleven Patent Rights, without Roche taking into account the payment reductions under this Agreement that would occur if any such Patent Rights were not to exist or if any applicable Composition of Matter Claim were not to exist.

(b) Should Roche decide that it does not desire to Handle a Primary Eleven Patent Right, it shall promptly advise Eleven thereof in writing in sufficient time as is reasonably needed for Eleven to not lose any rights with respect to such Primary Eleven Patent Right. Eleven may thereafter Handle the same at Eleven's own cost, to the extent that Eleven desires to do so.

13.1.2 After Exercising Buy-out Option

After such time as Roche exercises a Buy-out Option, Roche may Handle all Primary Eleven Patent Rights (except those which Roche previously opted not to Handle under Section 13.1.1) at its own expense and discretion and without consultation with Eleven. Roche shall not be required to use Commercially Reasonable Efforts to Handle such Primary Eleven Patent Rights and shall not be required to advise Eleven if it desires to discontinue the Handling of a given Primary Eleven Patent Right or be required to allow Eleven to continue Handling. If Roche so requests, Eleven will, at Roche's expense, assign to Roche all of Eleven's ownership rights under such Primary Eleven Patent Rights designated by Roche that are owned by Eleven (such rights, upon assignment, the " **Eleven Assigned Patent Rights** "). Eleven shall provide copies of lab notebooks and inventor contact information as may be necessary for Roche to assume ownership responsibility for such Eleven Assigned Patent Rights.

13.2 Prosecution of Select Non-Prosecution Patent Rights

Eleven shall, at its own expense and discretion, Handle Non-Prosecution Patent Rights, except with respect to the Non-Prosecution Patent Rights listed in Appendix 13.2 (the " **Select Non-Prosecution Patent Rights** "), (i) Eleven will not claim any Eleven Compounds *per se* in the Select Non-Prosecution Patent Rights without the consent of Roche and (ii) Eleven will timely consult with Roche (unless Roche waives such right in writing) on the Handling of the Select Non-Prosecution Patent Rights so as to provide Roche with an opportunity to recommend any changes (which changes Eleven may not unreasonably refuse) that Roche reasonably believes are necessary to avoid damage to the Core Patent Rights listed in the Appendix 1.30 table headed "Improved IL-6 Antibodies" and patents and patent applications claiming priority from such Patent Right and any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or

continuation-in-part of any of the foregoing; provided, however, that Eleven may abandon any Select Non-Prosecution Patent Right without consultation with or consent of Roche.

13.3 Patent Coordination Liaison

Where the Parties need to consult with or seek the assistance of each other on the Handling of Patent Rights, the Parties shall each nominate a patent liaison and shall adopt procedures for interacting on patent matters. Each Party shall reasonably cooperate and assist each other to effect the transfer of responsibility for such Handling of Patent Rights, and shall reasonably assist the other Party in such Handling where needed, including the execution of necessary authorizations and assignments and take such other actions as may be reasonably requested in the Handling of such Patent Rights.

13.4 Infringement

Each Party shall promptly provide written notice to the other Party during the Agreement Term of any

(i) known infringement or suspected infringement by a Roche Group Third Party of any Valid Claim of the Primary Eleven Patent Rights through the unauthorized manufacture, use, sale or importation of a Licensed Compound or Licensed Product, or

(ii) known or suspected unauthorized use or misappropriation by a Roche Group Third Party of any Eleven Know-How in the unauthorized manufacture, use, sale or importation of a Licensed Compound or Licensed Product by such Roche Group Third Party,

and shall provide the other Party with all factual evidence in its possession supporting such infringement or unauthorized use or misappropriation.

Within sixty (60) days after Roche provides or receives such written notice or such shorter period of time as is reasonably necessary for Eleven to avoid loss of material enforcement rights or remedies (unless such shorter period is not possible under the circumstances) (“ **Decision Period** ”), Roche, in its sole discretion, shall decide whether or not to initiate a suit or action in the Territory regarding such infringement or unauthorized use or misappropriation and shall notify Eleven of its decision in writing (“ **Suit Notice** ”).

If Roche decides to bring a suit or take action, once Roche provides Suit Notice, Roche shall commence such suit or take such action. In the event that Roche (i) does not in writing advise Eleven within the Decision Period that Roche will commence suit or take action, or (ii) fails to commence suit or take action within a reasonable time after providing Suit Notice, Eleven shall thereafter have the right (subject to Roche's written consent, which except for Eleven Assigned Patent Rights is not to be unreasonably withheld) to commence suit or take action and shall provide written notice to Roche of any such suit commenced or action taken by Eleven.

Upon written request, the Party bringing suit or taking action (" **Initiating Party** ") shall keep the other Party informed of the status of any such suit or action and shall provide the other Party with copies, to the extent the Initiating Party is lawfully permitted to do so, of all substantive documents or communications filed in such suit or action. The Initiating Party shall have the sole and exclusive right to select counsel for any such suit or action.

The Initiating Party shall, except as provided below, pay all expenses of the suit or action, including the Initiating Party's attorneys' fees and court costs (and such costs of the other Party if participating at the Initiating Party's request). Unless otherwise agreed by the Parties, and subject to the Parties' respective obligations under Article 15, all monies recovered upon the final judgment or settlement of any action described in this Section 13.4 shall be used as follows:

(a) First, to reimburse the Initiating Party for its costs and, if any remains, to the other Party for any advisory counsel fees and costs not already reimbursed by the Initiating Party; and

(b) Second,

(i) if a member of the Roche Group is the Initiating Party,

(A) any remaining amount that represents compensation for lost sales, a reasonable royalty or lost profits, shall be retained by or paid to the Initiating Party; provided, however, any such amount (after relevant adjustment to convert to Net Sales of Products) shall be subject to the royalty obligations set forth in Section 9.3; and

(B) any remaining amount that represents additional damages (e.g., enhanced or punitive damages) shall be allocated to Roche; and

(ii) if Eleven is the Initiating Party, the balance, if any, shall be allocated seventy five percent (75%) to the Initiating Party, and twenty five percent (25%) to the other Party.

If the Initiating Party believes it is reasonably necessary or desirable to obtain an effective remedy, upon written request the other Party agrees to be joined as a party to the suit or action but shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to the suit or action, all of which shall be at the Initiating Party's expense. At the Initiating Party's written request, the other Party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance. The other Party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.

The Initiating Party may settle, consent to judgment or otherwise voluntarily dispose of the suit or action (" **Settlement** ") without the written consent of the other Party but only if such Settlement can be achieved without adversely affecting the other Party (including any of its Patent Rights). If a Settlement could materially adversely affect the other Party, then the written consent of the other Party would be

required, which consent shall not be unreasonably withheld, however if the other Party is unable to timely respond, then such consent shall be deemed as granted.

For clarity, Roche shall be solely responsible, at its own expense and discretion, for responding to the infringement of any Eleven Assigned Patent Rights, and will receive all monies recovered upon the final judgment or settlement of any action taken by Roche in connection therewith. If a Settlement could materially adversely affect Eleven, then the written consent of Eleven would be required, which consent shall not be unreasonably withheld, however if Eleven is unable to timely respond, then such consent shall be deemed as granted. Eleven will reasonably assist Roche in any such actions, at Roche's expense.

13.5 Defense

Subject to Article 15, if an action for infringement is commenced against either Party, its licensees or its sublicensees related to the discovery, development, manufacture, use or sale of a Product, then Roche shall have the right (but not the obligation) to defend such action at its own expense, and Eleven shall assist and cooperate with Roche, at Roche's expense, to the extent necessary in the defense of such suit. Roche shall have the right to settle the suit or consent to an adverse judgment thereto, in its sole discretion, so long as such settlement or adverse judgment does not adversely affect the rights of Eleven. Roche shall assume full responsibility for the payment of any award for damages, or any amount due pursuant to any settlement entered into by it with such Third Party.

13.6 Common Interest Disclosures

With regard to any information or opinions about intellectual property disclosed pursuant to this Agreement between the Parties, the Parties agree that, to the extent possible under Applicable Law, they have a common legal interest in (i) determining whether, and to what extent, Third Party intellectual property rights may affect Compounds or Products and (ii) defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to Compounds or Products. Accordingly, the Parties agree that, to the extent possible under Applicable Law, (i) all such relevant information or opinions obtained by Eleven and Roche from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of the Agreement; (ii) all such information and materials will be treated as protected by the attorney-client privilege, the work product privilege, the joint defense privilege, the common interest privilege, and any other privilege or immunity that may otherwise be applicable; (iii) by sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Nothing in this Section 13.6 shall prevent either Roche or Eleven from claiming a common interest privilege in any other matter properly subject to that privilege. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Party's prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against any other Party.

It is expressly understood that nothing contained in this Section 13.6 shall limit the right of either Party to disclose to anyone (or withhold disclosure from anyone) any of their own documents and information, as they see fit.

13.7 Biosimilar or interchangeable biological products

Notwithstanding anything herein to the contrary, within four (4) years after the approval of a Product that has been licensed in the US as a biological product under 42 USC §262(a), and as may be needed from time to time thereafter, upon request by Roche, the Parties shall consult as to potential strategies with respect to unexpired US Primary Eleven Patent Rights Controlled by Eleven that Cover the Product. Specifically, in anticipation of a receipt by the Product's reference product sponsor (" **Reference Product Sponsor** ") of a biosimilar or interchangeable product application pursuant to the Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148), the Parties will discuss the Reference Product Sponsor's likely course of action with regard to US Primary Eleven Patent Rights in the procedural steps set forth under 42 USC §262(l), including a general plan for timely communication between the Parties in light of the statutory response deadlines.

13.8 Patent Term Extensions

The Parties shall use Commercially Reasonable Efforts to obtain all available patent term extensions, adjustments or restorations, or supplementary protection certificates (" **SPCs** ", and together with patent term extensions, adjustments and restorations, " **Patent Term Extensions** ") for Primary Eleven Patent Rights. Eleven shall execute such authorizations and other documents and take such other actions as may be reasonably requested by Roche to obtain such Patent Term Extensions, including designating Roche as its agent for such purpose as provided in 35 USC § 156. All filings for such Patent Term Extensions shall be made by Roche; provided, that in the event that Roche elects not to file for a Patent Term Extension for a Primary Eleven Patent Right, Roche shall (i) promptly inform Eleven of its intention not to file and (ii) grant Eleven the right to file for such Patent Term Extension. Each Party shall execute such authorizations and other documents and take such other actions as may be reasonably requested by the other Party to obtain such extensions. The Parties shall cooperate with each other in gaining patent term restorations, extensions or SPCs wherever applicable to such Primary Eleven Patent Rights.

13.9 Consent to File Patent Applications

Eleven hereby provides consent under Section 4(f) of the Material Transfer Agreement by and between the Parties effective November 18, 2015, as amended (the " **MTA** ").

14. Representations and Warranties

14.1 Eleven Representations and Warranties

Eleven represents and warrants to Roche, in each case as of the Signature Date (except with respect to any such statement that is expressly made as of a specific date, which representation and warranty shall be as of such date):

14.1.1 Safety Data

(a) Eleven has disclosed to Roche and, to the extent set forth in Section 5.2, will promptly disclose to Roche the results of all preclinical testing of Licensed Product in its Control.
(b) Eleven has not conducted human clinical testing of any Licensed Product. In accordance with Section 5.2, Eleven will disclose to Roche all information in its Control concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof in humans with respect to Licensed Product.

14.1.2 Ownership of Patent Rights

Eleven is the exclusive owner of all right, title and interest in, or is the exclusive licensee of, the Eleven Base Patent Rights existing on the Signature Date. Appendix 1.30 and Appendix 13.2 collectively contain a complete and accurate list of all Patent Rights Controlled by Eleven as of the Signature Date that Cover Eleven Compounds. Between the Signature Date and the Effective Date, Eleven will have used Commercially Reasonable Efforts to prosecute or maintain the Core Patent Rights and has not granted and will not grant rights to any Third Party under the Eleven Base Patent Rights that conflict with the rights granted to Roche hereunder.

14.1.3 Third Party Eleven IP

To the knowledge of Eleven, the Third Party Eleven IP does not Cover or relate to Compounds or Products, and the scope of the Third Party Eleven IP does not overlap with the Eleven Base Patent Rights.

14.1.4 Inventors

Eleven warrants that the inventors of the inventions disclosed or claimed in Eleven Patent Rights have transferred to Eleven full ownership of the Patent Rights licensed under this Agreement.

14.1.5 Grants

To the best of Eleven's knowledge and belief, Eleven has the lawful right to grant Roche and its Affiliates the rights and licenses described in this Agreement, assuming that no filing is required under the Hart Scott Rodino Antitrust Improvements Act of 1976 (the " **HSR Act** ").

14.1.6 Authorization

The execution, delivery and performance of this Agreement by Eleven and all instruments and documents to be delivered by Eleven hereunder, subject, in each case, to the receipt of the Required Company Stockholder Vote and assuming that no filing is required under the HSR Act: (i) are within the corporate power of Eleven; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of incorporation of Eleven; (iv) to the knowledge of Eleven, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Eleven is a party or by which Eleven or any of its property is bound; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained

previously (other than filings of reports, schedules or materials with the Securities and Exchange Commission or pursuant to any applicable state securities laws and filings with Regulatory Authorities with respect to Products), except, in the case of clauses (iv), (v) and (vi), for any such violations, and for any filings, registrations or consents not obtained or made, that, individually or in the aggregate, are not reasonably likely to have a material adverse effect on the financial condition of Eleven or on the ability of Eleven to perform its obligations hereunder.

14.1.7 Validity of Patent Rights

Eleven is not in possession of information that Eleven reasonably believes could render invalid or unenforceable any claims that are in any of the Primary Eleven Patent Rights existing on the Signature Date. Eleven has no knowledge of any inventorship disputes concerning any Eleven Patent Rights.

14.1.8 Ownership and Validity of Know-How

The Eleven Know-How is legitimately in the possession of Eleven and has not been misappropriated from any Third Party. Eleven has taken reasonable measures to protect the confidentiality of the Eleven Know-How.

14.1.9 No Claims

There are no claims or investigations, pending or, to Eleven's knowledge, threatened against Eleven, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement that would materially and adversely affect Eleven's ability to perform its obligations hereunder.

14.1.10 Scope of License

On the Signature Date and Effective Date, Eleven has not granted any rights to another entity that would reduce the scope of the license to Roche contemplated by this Agreement.

14.2 Roche Representations and Warranties

Roche represents and warrants to Eleven, in each case as of the Signature Date (except with respect to any such statement that is expressly made as of a specific date, which representation and warranty shall be as of such date):

14.2.1 Authorization

The execution, delivery and performance of this Agreement by Roche and all instruments and documents to be delivered by Roche hereunder: (i) are within the corporate power of Roche; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of formation or limited liability company agreement of Roche; (iv) to the knowledge of Roche, will not violate any law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Roche is a party or by which Roche or any of its property

is bound; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other person, which has not been made or obtained previously (other than filings with the Securities and Exchange Commission or pursuant to any applicable state securities laws and filings with Regulatory Authorities with respect to Products), except, in the case of clauses (iv), (v) and (vi), for any such violations, and for any filings, registrations or consents not obtained or made, that, individually or in the aggregate, are not reasonably likely to have a material adverse effect on the financial condition of Roche or on the ability of Roche to perform its obligations hereunder.

14.2.2 No Claims

There are no claims or investigations, pending or, to Roche's knowledge, threatened against Roche, at law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement that would materially adversely affect Roche's ability to perform its obligations hereunder.

14.3 No Other Representations

EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES, EXPRESS, STATUTORY OR IMPLIED AND WHETHER WRITTEN OR ORAL RELATED TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS OR NON-INFRINGEMENT. ROCHE HAS RELIED SOLELY UPON ITS OWN INVESTIGATION AND ANALYSIS AND THE REPRESENTATIONS AND WARRANTIES OF ELEVEN EXPRESSLY SET FORTH IN THIS AGREEMENT.

15. Indemnification

15.1 Indemnification by Roche

Roche shall indemnify, hold harmless and defend Eleven and its directors, officers, employees and agents (collectively, " **Eleven Indemnitees** ") from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Eleven becomes legally obligated to pay, because of a claim by a Roche Group Third Party, to the extent resulting from the breach of the Agreement by Roche or activities related to the Licensed Product (e.g., product liability claims) conducted by or on behalf of a member of the Roche Group (other than by Eleven Indemnitees), except to the extent such losses, expenses, costs and amounts are due to the breach of the Agreement by Eleven or the gross negligence or willful misconduct or failure to act of Eleven Indemnitees.

15.2 Indemnification by Eleven

Eleven shall indemnify, hold harmless and defend Roche and its directors, officers, employees and agents (collectively, " **Roche Indemnitees** ") from and against any and all losses, expenses, cost of

defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Roche becomes legally obligated to pay, because of a claim by a Roche Group Third Party, to the extent resulting from the breach of the Agreement by Eleven or activities related to the Licensed Product (e.g., product liability claims) conducted by or on behalf of Eleven (other than by Roche Indemnitees or any member of the Roche Group), except to the extent such losses, expenses, costs and amounts are due to the breach of the Agreement by Roche or the gross negligence or willful misconduct or failure to act of Roche Indemnitees or any member of the Roche Group.

15.3 Procedure

In the event of a claim by a Roche Group Third Party against a Party entitled to indemnification under this Agreement (" **Indemnified Party** "), the Indemnified Party shall promptly notify the other Party (" **Indemnifying Party** ") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

16. Liability

16.1 Limitation of Liability

(a) Subject to Article 3, neither Party shall be liable to the other Party as a result of failure or delay to develop or commercialize the Licensed Compound or the Licensed Product, as applicable, including but not limited to, a) a delay in timelines, or b) delay or failure to recruit patients, or c) a change in its respective study protocols, or d) failure of the other Party to obtain Regulatory Approval for the Licensed Compound or the Licensed Product, as applicable.

(b) EXCEPT FOR INDEMNIFICATION UNDER ARTICLE 15, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES, OR LOST PROFITS, IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER REGARDLESS OF THE FORM OF ACTION THROUGH WHICH ANY OF THE FOREGOING ARE SOUGHT.

16.2 Coordination

Roche Basel and Roche US shall coordinate the exercise of Roche's rights under this Agreement. Roche Basel and Roche US shall be jointly and severally liable for Roche's obligations under this Agreement.

17. Obligation Not to Disclose Confidential Information

17.1 Non-Use and Non-Disclosure

During the Agreement Term and for five (5) years thereafter, a Receiving Party shall (and shall require its Affiliates to) (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to disclose such Confidential Information to Third Parties, without the Disclosing Party's prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations or exercising its rights under this Agreement.

17.2 Permitted Disclosure

Notwithstanding the obligation of non-use and non-disclosure set forth in Section 17.1, the Parties recognize the need for certain exceptions to this obligation, specifically set forth below, with respect to press releases, patent rights, publications, and certain commercial considerations.

17.3 Press Releases

(a) The Parties may issue solely or jointly the press releases announcing the existence and selected key terms of this Agreement, in a form substantially similar to the templates attached as Appendix 17.3.

(b) Eleven shall only issue other press releases related to the activities contemplated by this Agreement that either (i) have been approved by Roche or (ii) are required to be issued by Eleven as a matter of law based on advice of legal counsel. In all such circumstances, Eleven shall provide Roche with a draft press release at least two (2) weeks prior to its intended publication for Roche's review. During such period, Roche shall (i) approve the draft press release and permit Eleven to issue the press release, (ii) contact Eleven to discuss modification to the draft press release, or (iii) contact Eleven and disapprove the press release. If Roche asks for modification, then Eleven shall either make such modification or work with Roche to arrive at a press release that Roche approves.

(c) Notwithstanding anything else to the contrary in this Agreement, Eleven may issue press releases or announcements, make filings or submissions or otherwise publicly disclose information regarding this Agreement and the transactions contemplated hereby without the prior written consent of Roche to the extent required by Applicable Law or the rules or regulations of any applicable U.S. or non-U.S. securities exchange or regulatory governmental body to which it is subject to or submits to, including any disclosures contained in proxy or other similar materials issued in connection with the Stockholder Voting Proposal; provided, however, the issuance by Eleven of any such press release without following the procedures of Section 17.3(b) must be based on advice of legal counsel that the release was required to be issued by Eleven as a matter of law. Notwithstanding the foregoing, in all such cases Eleven shall use Commercially Reasonable

Efforts to provide Roche an advance draft press release, announcement, filing or submission as applicable as soon as reasonably practicable and consider in good faith Roche's reasonable and timely comments prior to publicly issuing its final version.

(d) To the extent the content of any press release or other announcement has been made in accordance with this Section 17.3 or with Section 17.4, no separate approval shall be required in respect of such content to the extent replicated in whole or in part in any subsequent press release or other announcement.

(e) To ensure communication alignment, responses (if any) to inquiries by media or other Third Parties (other than inquiries by any governmental authority, body, agency or other instrumentality) after issuance of a permitted press release by Eleven (solely or jointly with Roche) shall consist solely of the press release language or shall follow the response guidelines that may be mutually developed by the Parties.

17.4 Commercial Considerations

(a) After the Effective Date, nothing in this Agreement shall prevent Roche or its Affiliates from disclosing Confidential Information of Eleven to (i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Product in the Territory, (ii) Third Parties acting on behalf of Roche, to the extent reasonably necessary for the development, manufacture or sale of Product in the Territory, or (iii) Third Parties to the extent reasonably necessary to market the Product in the Territory.

(b) Either Party may disclose this Agreement to actual or potential licensees, sublicensees, acquirers or investors under terms of confidentiality no less stringent than in this Agreement.

(c) The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such Confidential Information is required to be disclosed by the Receiving Party to comply with Applicable Law, to defend or prosecute litigation or to comply with governmental regulations, provided that the Receiving Party provides prior written notice of such disclosure to the Disclosing Party, if possible, and, to the extent practicable, takes reasonable and lawful actions to minimize the degree of such disclosure.

(d) The Parties acknowledge that either or both Parties may be obligated to make one or more filings (including to file a copy of this Agreement) with the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority. Each Party will be entitled to make such a required filing, provided that it will (i) submit in connection with such filing a copy of this Agreement in a form mutually agreed by the Parties in advance or, if despite the commercially reasonable efforts of Eleven a form mutually agreed by the Parties cannot be agreed in advance, redacted to the extent permitted by Applicable Law (the " **Redacted Agreement** "), (ii) request, and use commercially reasonable efforts consistent with Applicable Laws to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in

the Redacted Agreement, for a period of at least ten (10) years, (iii) to the extent consistent with Applicable Law, promptly deliver to the other Party any written correspondence received by it or its representatives from the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority with respect to such confidential treatment request and promptly advise the other Party of any other material communications between it or its representatives with the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority with respect to such confidential treatment request, (iv) upon the written request of the other Party, if legally justifiable, request an appropriate extension of the term of the confidential treatment period, and (v) if the U.S. Securities and Exchange Commission (or equivalent foreign agency) or a governmental authority requests any changes to the redactions set forth in the Redacted Agreement, use commercially reasonable efforts consistent with Applicable Laws to support the redactions in the Redacted Agreement as originally filed and not agree to any changes to the Redacted Agreement without, to the extent practical, first discussing such changes with the other Party and taking the other Party's comments into consideration when deciding whether to agree to such changes (provided that a Party will only be required to make such efforts to support such redactions once). For clarity, following a request from a governmental authority to change the redactions requested by a Party, a Party will not be required pursuant to the provisions of this Section 17.4(d) to again request the redactions rejected by the applicable governmental authority. Each Party will be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

18. Agreement Expiration and Termination

18.1 Commencement and Expiration

This Agreement shall commence upon the date hereof (except for Sections 2.2 and 2.3, Articles 3-15 (except for Sections 9.5 and 14.3, which shall be effective as of the Signature Date) and Sections 18.2.1-18.2.4, 18.3, 18.4, 21.5 and 21.12 which shall commence as of the Effective Date, and except for such other provisions of this Agreement which expressly commence as of a specific date, which shall commence as of such date) and, unless earlier terminated under Section 18.2, shall expire on the Expiration Date.

18.2 Termination

18.2.1 Termination for Material Breach After the Effective Date

After the Effective Date, a Party (" **Non-Breaching Party** ") shall have the right to terminate this Agreement in its entirety or on a country-by-country basis in the event the other Party (" **Breaching Party** ") is in breach of any of its material obligations under this Agreement. The non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach and the countries in which the Non-Breaching Party intends to have this Agreement terminate. The Breaching Party shall have a period of ninety (90) days after such written notice is provided (" **Peremptory Notice Period** ") to cure such breach. If the Breaching Party has a *bona fide* dispute as to whether such breach

occurred or has been cured, it will so notify the Non-Breaching Party, and the expiration of the Peremptory Notice Period shall be tolled until such dispute is resolved pursuant to Sections 21.2 or 21.3. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in its entirety or such identified countries effective as of the expiration of the Peremptory Notice Period.

18.2.2 Termination by Roche without Cause After the Effective Date

After the Effective Date, Roche shall have the right to terminate this Agreement at any time as a whole or on a Product-by-Product or country-by-country basis upon ninety (90) days prior written notice before First Commercial Sale in the Territory or upon one hundred eighty (180) days prior written notice after the First Commercial Sale in the Territory. The effective date of termination under this Section 18.2.2 shall be the date ninety (90) days (or one hundred eighty (180) days as the case may be) after Roche provides such written notice to Eleven.

18.2.3 Termination by Eleven for Development Discontinuation After the Effective Date

After the Effective Date, Eleven shall have the right to terminate this Agreement upon written notice if, prior to the first BLA Filing for a Licensed Product, the Roche Group has discontinued material development of all Licensed Products for the previous twelve (12) consecutive months, and such discontinuations were not due to events outside of the reasonable control of the Roche Group (including actions taken by Regulatory Authorities, or any Third Party litigation relating to the safety of a Licensed Product).

18.2.4 Termination for Eleven Debarment

After the Effective Date, Roche shall have the right to terminate this Agreement upon written notice for Eleven's debarment in accordance with Section 21.5.

18.2.5 Termination by a Party Prior to the Effective Date

(a) Eleven will inform Roche of the date of the Company Meeting at which a vote of the Stockholder Voting Proposal is to be taken. Eleven will inform Roche of the results of the Company Meeting at which a vote on the Stockholder Voting Proposal was taken within one (1) Business Day of such meeting. Eleven will inform Roche within one (1) Business Day of a decision by the Board of Directors of Eleven to approve or recommend to the stockholders any Alternative Transaction from a Qualified Person.

(b) Prior to the Effective Date, if, at the Company Meeting at which a vote on the Stockholder Voting Proposal is taken, the Required Company Stockholder Vote in favor of the Stockholder Voting Proposal is not obtained, this Agreement shall automatically terminate as of the date of such Company Meeting at which such vote on the Stockholder Voting Proposal was taken.

(c) Prior to the Effective Date, Roche shall have the right to terminate this Agreement upon written notice if the Company Meeting at which a vote on the Stockholder Voting Proposal is taken does not occur on or prior to the seventy-fifth (75th) day following the Signature Date.

(d) Prior to the Effective Date, either Party shall have the right to terminate this Agreement upon written notice if the Board of Directors of Eleven shall have approved or recommended to the stockholders any Alternative Transaction from a Qualified Person.

18.3 Consequences of Termination

This Section 18.3 only applies to termination under Section 18.2.1-18.2.4.

18.3.1 Termination for Eleven Breach or Debarment

Upon any termination by Roche under Section 18.2.1 (material breach by Eleven) or 18.2.4 (Eleven debarment), the rights and licenses granted by Eleven to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by-Product basis, as applicable, on the effective date of termination. In the event of a material breach by Eleven or Eleven's debarment, if the Roche Group elects not to terminate this Agreement, Roche shall be entitled to seek remedies, including but not limited to damages and reduction of payment obligations in Article 9, subject to the terms and conditions of this Agreement.

18.3.2 Roche Activated Termination

Upon any Roche Activated Termination, the rights and licenses granted by Eleven to Roche under this Agreement shall terminate in their entirety or on a country-by-country and Product-by-Product basis, as applicable, on the effective date of termination. The Continuation Election Evaluation Process corresponding to an Involuntary Termination shall begin on the effective date of termination; the Continuation Election Evaluation Process corresponding to a Voluntary Termination shall begin on the date Roche provides its notice of termination to Eleven (each such date, a " **CEEP Start Date** ").

During the Continuation Election Evaluation Process, Roche shall continue activities, including preparatory activities, ongoing as of the CEEP Start Date with respect to the relevant Returnable Product(s). However, Roche shall not be obliged to initiate any new activities not ongoing as of the CEEP Start Date except as expressly set forth herein and except that Roche shall initiate such new activities at Eleven's reasonable written request and expense. Where possible the Alliance Directors will cooperate with each other to facilitate meeting Eleven's reasonable requests for information and continuation of activities reasonably needed for Eleven's bona fide intention to continue development of the Returnable Product(s) while minimizing Roche's investment in labor and expenses during the Continuation Election Evaluation Process.

Within ten (10) days after the CEEP Start Date, Roche shall have the opportunity (but not the obligation) to provide Eleven with either such information as Roche would like Eleven to consider or a notification waiving the right to provide such information. Within twenty (20) days after the CEEP Start Date, Eleven shall communicate to Roche either (x) a non-binding statement of continued interest in developing the specified Returnable Product(s) or (y) a binding waiver of Eleven's right to submit a Continuation Election Notice. If Eleven elects to communicate the latter or fails to communicate with Roche, then

Eleven shall have been deemed to have not provided a timely Continuation Election Notice and Section 18.3.4.1 shall apply. If Eleven elects to communicate the former, Roche shall promptly populate a secure data room with such material information pertaining to the applicable Roche Group's development, manufacturing and commercialization activities for such Returnable Product(s) as is reasonably necessary for Eleven to make an informed decision as to whether to submit a Continuation Election Notice, which data room shall be fully populated and opened for Eleven's access no later than thirty (30) days after Eleven's communication of a non-binding indication of interest under clause (x) above. Roche shall make the relevant personnel available for Eleven's reasonable follow-up questions and requests pertaining to such information, and Roche shall disclose such additional materials as are reasonably necessary to respond to Eleven's requests. Notwithstanding anything in this Section, such data room and personnel follow-up is not intended to provide Eleven with a similar scope of information or follow-up as would be required and commensurate with types of investment and diligence commitment Roche has made to Eleven under this Agreement, nor is it a substitute for Roche Transfer Activities that are reimbursed in accordance with Section 18.3.4.3(d); rather it is intended to be a process to minimize Roche's continuation activity costs where not required; provided, however, that the data provided in the data room must be adequate for Eleven to make a reasonably informed decision regarding the Continuation Election Notice. If Eleven desires to continue development or commercialization of Returnable Product(s), Eleven shall give a Continuation Election Notice to Roche within forty (40) days after the data room is reasonably populated and open for Eleven's access; if during such forty (40) day period, Eleven does not have a *bona fide* interest in pursuing development, Eleven shall promptly notify Roche.

After Roche's receipt of a timely Continuation Election Notice from Eleven, to the extent reasonably requested by Eleven with respect to the Returnable Product(s) specified in such Continuation Election Notice:

a) Roche shall, and shall ensure that its Affiliates shall, (and, to the extent Roche or any of its Affiliates has the right to do so and to the extent such sublicensees do not take a direct license in accordance with Section 18.3.3, shall require the other members of the Roche Group to,) promptly transfer to Eleven all regulatory filings and approvals, all final pre-clinical and clinical study reports and clinical study protocols, and all data, including clinical data, in their possession and control related to Returnable Product(s) necessary for Eleven to continue to develop and commercialize the Returnable Product(s). All data shall be transferred in the form and format in which it is maintained by the relevant member of the Roche Group. Original paper copies shall only be transferred, if legally required. Roche shall not be required to prepare or finalize any new data, reports or information solely for purposes of transfer to Eleven.

b) Roche shall, and shall ensure that its Affiliates shall, (and, to the extent Roche or any of its Affiliates has the right to do so and to the extent such sublicensees do not take a direct license in accordance with Section 18.3.3, shall require the other members of the Roche Group to,) make reasonable efforts to promptly assign all clinical trial agreements, to the extent such agreements have not been cancelled, are assignable without subjecting Roche to any material liability and are assignable without Roche paying any consideration (unless Eleven agrees to pay such consideration) or commencing litigation in order to effect an assignment of any such agreement.

c) Eleven shall, upon such transfer, have the right to disclose such filings, approvals and data to (i) governmental agencies of the country to the extent required or desirable to secure government

approval for the development, manufacture or sale of Returnable Product(s) in the country; (ii) Third Parties acting on behalf of Eleven, its Affiliates or licensees, to the extent reasonably necessary solely for the development, manufacture, or sale of Returnable Product(s) in the country, or (iii) Third Parties to the extent reasonably necessary to market Returnable Product(s) in the country.

d) In exchange for Roche's transfer of such items that were not originally provided from Eleven to Roche under this Agreement (i.e., created or developed by or on behalf of Roche), Eleven shall pay Roche a royalty on all net sales (as determined by reasonable accounting methods) of such Returnable Product(s) by Eleven, its Affiliates or licensees or sublicensees to which Eleven has licensed or sublicensed rights other than through a Compulsory Sublicense, *mutatis mutandis* , for such Returnable Product(s) (other than licensees that have a direct license in accordance with Section 18.3.3), with the royalty rate as follows:

Status of Returnable Product at time of termination	Royalty rate
Phase II Study Initiated	2%
Phase III Study Initiated	5%
First Commercial Sale in US or anywhere in the EU	10%

Such royalties shall be paid on a Returnable Product-by-Returnable Product and country-by-country basis commencing on the first commercial sale of the Returnable Product in such country by Eleven, or any of its Affiliates or any of such of its licensees or sublicensees (other than an entity that is or was a member of the Roche Group) and ending ten (10) years after the first commercial sale of the Returnable Product in such country by any entity (including a member of the Roche Group). Royalties may be reduced upon entry of a biosimilar product in accordance with the reduction structure set forth in Section 9.3.5, and with respect to any other reductions described in Sections 9.3.3, 9.3.4 and 9.3.6, as if applied to Eleven, its Affiliates and licensees or sublicensees in lieu of the Roche Group. Such payments shall be subject to the reporting and auditing obligations comparable to those set forth in this Agreement, except with Eleven as the licensee instead of Roche.

e) In connection with such transfer, and in all cases subject to Section 18.3.4.3, Eleven shall have a non-exclusive license, sublicensable through multiple tiers, under the Roche Patent Rights and Roche Know-How, solely to the extent necessary to allow Eleven, its Affiliates or licensees or sublicensees to register, have registered, develop, manufacture, have manufactured, use, offer to sell, sell, promote, export and import the Base Returnable Product associated with each applicable Returnable Product specified in such Continuation Election Notice and all associated applicable Modified Returnable Product(s) for such Base Returnable Product in the applicable country(ies), *with the proviso* that
   (i) with respect to Early Returnable Products, unless Roche specifically agrees to the contrary, such license shall not extend to Proprietary Manufacturing IP for Early Returnable Products;
   (ii) with respect to Returnable Products other than Early Returnable Products, such license does not apply to Proprietary Manufacturing IP for so long as Roche elects to manufacture and supply such Returnable Product under Section 18.3.4.2(c), and if Roche transfers the process to one or more Third Party CMOs acceptable to Roche under conditions of confidentiality and non-use acceptable to Roche in accordance with Section 18.3.4.2(c), such license of

Proprietary Manufacturing IP shall not extend to Eleven and will instead be limited to such Third Party CMO(s) for the sole purpose of manufacturing such Returnable Products on behalf of Eleven, Eleven's Affiliates or Eleven's licenses or sublicensees.

Eleven shall ensure that all of the applicable terms and conditions of this Agreement shall apply to its Affiliates and licensees and sublicensees to the same extent as they apply to Eleven for all purposes, and Eleven assumes full responsibility for the performance of all obligations and observances of all terms so imposed on such Affiliates, licensees and sublicensees. Eleven shall provide Roche a copy of any such agreements with licensees and sublicensees which may be redacted to exclude financial terms and confidential information of Eleven or the licensee or sublicensee. For clarity, the licenses under this Section 18.3.2(e) shall not include any licenses that Roche has with a Third Party for which such grant would be prohibited or under which a member of the Roche Group would incur liability or financial obligations (unless Eleven agrees to pay such financial obligations) to such Third Party.

f) If requested by Eleven in writing, and solely to the extent Roche is able to do so truthfully, Roche will represent and warrant to Eleven that, as of the effective date of the termination, Roche and its Affiliates have not been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program in a manner that would materially impact the Returnable Products.

18.3.3 Direct License

Irrespective of anything to the contrary in this Agreement, any existing, permitted sublicense granted directly by Roche under Section 2.3.2 of this Agreement (and any further sublicenses thereunder) to any Third Party shall, upon the written request of Roche, remain in full force and effect to the extent that Roche had complied with its obligations under Section 2.3.2 with respect thereto, provided that (i) each such Sublicensee and any further sublicensees are not then in breach of its sublicense agreement (and, in the case of termination by Eleven for material breach by Roche, that neither such Sublicensee nor any further sublicensees caused the material breach that gave rise to the termination by Eleven); (ii) each such direct Sublicensee agrees to be bound to Eleven under all the terms and conditions of such sublicense agreement; and (iii) Eleven is provided with a true and complete copy of such sublicense agreement.

18.3.4 Other Obligations Applicable for Roche Activated Terminations

18.3.4.1 Obligations Related to Ongoing Activities

(a) If Eleven does not provide timely a Continuation Election Notice, then Roche (i) shall have the right to cancel all ongoing obligations with Third Parties with respect to any terminated Returnable Product under this Agreement and (ii) shall be permitted to complete, and be solely responsibility for, all non-cancellable obligations with Third Parties with respect to any terminated Returnable Product, but only at its own expense.

(b) If Eleven provides such timely Continuation Election Notice, then from the date of notice of termination until (i) the effective date of termination (in the event of a Voluntary Termination) and (ii) four (4) months after the effective date of termination (in the event of an Involuntary Termination), Roche shall continue activities, including preparatory activities, ongoing as of the date of notice of termination with respect to the relevant Returnable Products, at Roche's expense. However, Roche shall not be obliged to initiate any new activities not ongoing at the date of notice of termination except as expressly set forth herein.

(c) After the effective date of termination, Roche shall have no obligation to perform or complete any activities or to make any payments for performing or completing any activities under this Agreement, except as expressly stated herein.

In addition to the foregoing, upon the request of Eleven, Roche shall, and shall ensure that its Affiliates shall, and, to the extent Roche or any of its Affiliates has the right to do so, shall require the other members of the Roche Group to, complete, or promptly transition to Eleven or its designee, any Clinical Studies related to the Returnable Product(s) that are being conducted under any of their INDs for the Returnable Product(s) and are ongoing as of the effective date of termination; provided, however, that

(i) both Eleven and Roche in their reasonable judgment have concluded that completing any such Clinical Studies does not present an unreasonable risk to patient safety;
(ii) Roche shall have no obligation to recruit or enroll any additional patients after the effective date of termination; and
(iii) Subject to Section 18.3.4.1(b), Eleven agrees to reimburse Roche for all of its reasonable development costs that arise after the effective date of termination in completing or transitioning such Clinical Studies.

18.3.4.2 Obligations Related to Manufacturing

a) Clinical Supplies
If Eleven elects to develop the Returnable Product(s), Roche shall, at Eleven's request, transfer (i) all existing and available clinical material to Eleven at a price of Roche's fully burdened manufacturing cost and (ii) as part of the Roche Transfer Activities of Section 18.3.2, all existing documentation as to the quality of such clinical material that is reasonably required for further development activities. Roche shall have no obligation to perform any additional activities concerning the clinical supplies (e.g., retesting, analyses). Upon request, Roche shall notify Eleven of any issues concerning such materials that to Roche's knowledge might reasonably subject Eleven to liability through use of such materials, and Eleven may thereafter elect not to receive such materials. Eleven shall assume all liability for the use of such transferred material.

b) Commercial Supplies
If a Returnable Product is marketed in any country of Territory on the date of the notice of termination of this Agreement, upon the request of Eleven, Roche shall manufacture and supply such Returnable Product to Eleven for a period of eighteen (18) months from the effective date of the termination of this Agreement (unless such obligation is earlier terminated by Eleven) at a price of one hundred twenty-five percent (125%) of Roche's fully burdened manufacturing cost. Eleven shall use Commercially Reasonable Efforts to take over the manufacturing as soon as possible after the effective date of termination.

c) Option of Roche
Irrespective of the foregoing, Roche shall not be required to provide Proprietary Manufacturing IP with respect to Early Returnable Products. Roche will continue to supply Eleven with Returnable Products other than Early Returnable Products at a price of one hundred twenty-five percent (125%) of Roche's fully burdened manufacturing cost for a period, at Roche's election, of either (i) indefinitely (in which case the Parties will promptly and in good faith negotiate the non-financial terms of applicable supply and quality agreements, and Roche shall make good faith efforts to supply Eleven with such Returnable Products during such negotiation period) or (ii) until such time as Roche transfers the process to a Third Party CMO acceptable to Roche under conditions of confidentiality and non-use acceptable to Roche. If Roche elects to transfer the process to a Third Party CMO and Eleven requests an additional CMO be utilized (for reasons such as second source manufacturing, competitive pricing), Roche will make good faith efforts to accommodate such request and transfer the process to a second Third Party CMO acceptable to Roche under conditions of confidentiality and non-use acceptable to Roche.

18.3.4.3 Limitations on Grant-Backs; Transfer Expenses

For purposes of clarity, irrespective of anything to the contrary in this Agreement:

a) All transfers and licenses from Roche to Eleven or other obligations of Roche under Section 18.3 are solely with respect to Returnable Product(s) that are not Combination Product(s). Such transfers, licenses and obligations do not extend to
   (i) other therapeutically active ingredients or therapeutically active products, even if physically mixed, combined or packaged together with a Returnable Product, or
   (ii) with respect to Pre-Commercialized Returnable Products, delivery technologies that are proprietary to Roche (through ownership or license) (*with the proviso* that if Eleven would be unable to use any alternative delivery technology to commercialize such Pre-Commercialized Returnable Product, Roche will in good faith consider making such delivery technologies available to Eleven),

   even if a Returnable Product is intended (according to the investigation plan, proposed labeling or actual labeling, as applicable) for use with such other therapeutically active ingredients, therapeutically active products, or delivery technologies.

b) In connection with research studies, clinical trials or other activities associated with the development and commercialization of Returnable Products, Roche or other members of the Roche Group may have collected human samples and patient information that may contain personal identifiable information (" **Samples and PI Information** "). Legal and contractual restrictions may apply to such Samples and PI Information. Eleven acknowledges and accepts that, where Roche in good faith has reasonable concerns that Applicable Law or insufficient patient consent would prohibit the transfer of such Samples and PI Information or subject Roche to liability because of such transfer and subsequent use by Eleven, then Roche shall not be obliged to transfer such Samples and PI Information to Eleven.

c) Nothing in this Agreement shall be construed as granting Eleven any license under the Excluded Roche Patent Rights.

d) If Eleven issues a Continuation Election Notice, then Eleven shall reimburse Roche for all reasonable out-of-pocket costs and expenses (including FTE charges) incurred by or on behalf of Roche for transfer activities from Roche to Eleven under Section 18.3.2 (including costs associated with locating, assembling and populating information into the data room) (" **Roche Transfer Activities** ") within thirty (30) days after receipt of an invoice, with an invoice to be provided no more than once per Calendar Quarter; however transfer activities corresponding to the return of material remains, data, reports, records, documents, regulatory filings and Regulatory Approvals originally provided by Eleven to Roche no less than three (3) years prior to the effective date of termination (" **Eleven-Originated Transfer Activities** ") shall be returned to Eleven free of charge. If the Agreement was terminated due to a Voluntary Termination and Eleven desires Roche Transfer Activities other than Eleven-Originated Transfer Activities, Eleven shall make a payment to Roche of Two Hundred Fifty Thousand US Dollars (US$ 250,000) (" **Minimum Transfer Payment** ") within thirty (30) days after receipt of an invoice. The Minimum Transfer Payment shall be non-refundable, but shall be fully creditable against Eleven's reimbursement for the Roche Transfer Activities and payments under Section 18.3.2(d). Roche shall be under no obligation to provide Roche Transfer Activities (beyond the Eleven-Originated Transfer Activities) prior to receipt of the Minimum Transfer Payment, if applicable.

18.4 Royalty and Payment Obligations

Expiration or termination of this Agreement shall not release Roche from any obligation to pay royalties or make any payments to Eleven that are earned but not yet paid prior to the Expiration Date or effective date of termination, including milestone payments on events, and royalties on Sales, that occur prior to the Expiration Date or effective date of termination. Expiration of this Agreement as a result of Roche exercising a Buy-out Option shall not release Roche from the obligation to pay the fee associated with such Buy-out Option under Section 9.4. Except as set forth in this Section 18.4, termination of this Agreement by a Party, for any reason, will release Roche from any obligation to pay royalties or make any payments to Eleven under Sections 9.2 or 9.3 that would otherwise become payable on or after the effective date of termination (including, for clarity, any milestone payments on events, or royalties on Sales, that occur after the effective date of termination, but not prior to the effective date of termination).

18.5 Survival

To the extent then in effect as set forth in Section 18.1, Article 1 (Definitions, to the extent necessary to interpret this Agreement), Section 9.5 (Disclosure of Payments), Article 10 (Accounting and Reporting) (solely as applicable to amounts described in Section 18.4), Article 12 (Auditing), Section 14.3 (No Other Representations), Article 15 (Indemnification), Article 16 (Liability), Article 17 (Obligation Not to Disclose Confidential Information), Article 18 (Agreement Expiration and Termination) and Article 21 (Miscellaneous) (except for Sections 21.4(a)-(c) (Assignment and Change of Control)) shall survive any expiration or termination of this Agreement for any reason. If Roche exercises a Buy-out Option, Section 9.4 (Buy-out Options), Article 13 (Intellectual Property) and Article 20 (Bankruptcy) shall also survive.

19. Solicitation

Except as otherwise set forth in Article 17 and in this Article 19, until the earlier of the Effective Date and the termination of this Agreement in accordance with Section 18.2.5, Eleven shall not, and shall use its reasonable best efforts to cause its officers, directors, employees, investment bankers, attorneys or other agents or advisors (collectively, " **Representatives** ") not to, directly or indirectly:

(a) solicit, initiate or knowingly facilitate or knowingly encourage the submission of any proposal or offer from any Third Party for an Alternative Transaction;
(b) enter into or participate in any discussions or negotiations with, furnish any non-public information relating to the IL-6 program to, or afford access to the business, properties, assets, books or records of the IL-6 program to, any Third Party that, to Eleven's knowledge, is seeking to make, or has made, any proposal or offer for an Alternative Transaction, in each case relating to or in connection with an Alternative Transaction; or
(c) enter into any agreement with any person or entity (other than Roche) for an Alternative Transaction.

Notwithstanding the foregoing, Eleven may: (i) furnish non-public information relating to, and afford access to the business, properties, assets, books or records of, the IL-6 program to any Qualified Person (and the Representatives of any such Qualified Person), pursuant to a confidentiality agreement not materially less restrictive of the other party than the confidentiality obligations applicable to Roche pursuant to the NDA; (ii) engage in discussions or negotiations (including solicitation of revised proposals with respect to an Alternative Transaction) with any Qualified Person (and the representatives of such Qualified Person) with respect to a potential Alternative Transaction; (iii) amend or grant a waiver or release under, any standstill or similar agreement with respect to any capital stock of Eleven with any Qualified Person; or (iv) enter into an agreement with a Qualified Person with respect to an Alternative Transaction.

20. Bankruptcy

All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by Eleven to Roche are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, US Code (the " **Bankruptcy Code** ") licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. Unless Roche elects to terminate this Agreement, the Parties agree that Roche, as a licensee or sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, subject to the continued performance of its obligations under this Agreement.

21. Miscellaneous

21.1 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the state of Delaware, US, without reference to its conflict of laws principles.

21.2 Disputes

After the Effective Date, unless otherwise set forth in this Agreement, in the event of any dispute in connection with this Agreement, such dispute shall be referred to the respective executive officers of the Parties designated below or the Party's designee, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For Eleven: CEO

For Roche: Head of Roche Partnering

21.3 Jurisdiction; Arbitration

Prior to the Effective Date, each of the Parties (a) consents to submit itself to the exclusive jurisdiction of the Court of Chancery of the State of Delaware or, solely if such court lacks subject matter jurisdiction, United States District Court sitting in Wilmington, Delaware, with respect to any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court, (c) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court and (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement or any of the transactions contemplated by this Agreement in any other court, and each Party hereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such legal proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereby agrees that service of any process, summons, notice or document by U.S. registered mail to the respective addresses set forth in Section 21.13 shall be effective service of process.

After the Effective Date, should the Parties fail to agree within two (2) months after a dispute in connection with this Agreement has first arisen, it shall be finally settled by arbitration in accordance with the Rules of American Arbitration Association (AAA) as in force at the time when initiating the arbitration. The tribunal shall consist of three arbitrators. Each Party shall select one (1) arbitrator and the arbitrators shall select the third arbitrator. The place of arbitration shall be in the city of New York, New York, US. The language to be used shall be English. Notwithstanding anything to the contrary in this Agreement, a Party may seek temporary equitable relief in the form of specific performance, a temporary restraining order, a preliminary injunction or any other equitable remedy in any court of competent jurisdiction.

21.4 Assignment and Change of Control

Neither Party may assign its rights or obligations under this Agreement absent the prior written consent of the other Party, except to any of its Affiliates (provided that the assigning Party shall be responsible for the actions of its Affiliates) or in the context of a merger, an acquisition, a Change of Control, or a sale or other transaction involving all or substantially all of the assets of the Party seeking to assign. Any permitted assignment shall be binding on the successors of the assigning Party. Notwithstanding anything else herein to the contrary, Eleven may, without Roche's consent, assign, distribute, dividend or otherwise transfer its right to receive payment(s) from Roche under all or part of Article 9, provided, however, for clarity, Roche's right to pursue reduction of payments in the event of a material breach by Eleven shall not be impacted by such assignment, distribution, dividend or transfer; moreover this

right extends only to the right to receive payment, so all other rights (including the right to audit) shall remain with Eleven absent Roche's written consent.

If there is a Change of Control, then the following provisions shall apply and be in full force and effect:

(a) Eleven shall provide written notice to Roche within fifteen (15) days after completion of such Change of Control.

(b) The acquirer of or the successor to in connection with such Change of Control shall acknowledge in writing to Roche that the Eleven Know-How and the Primary Eleven Patent Rights are subject to the exclusive licenses to Roche for the research, development or commercialization of Compounds or Products, subject to the terms and conditions of this Agreement.

(c) If either Eleven or the Change of Control Group are engaged in the conduct of clinical studies or commercialization of competing ophthalmic products either at the time of the Change of Control or thereafter, then Roche may upon written request require Eleven and the Change of Control Group to institute a firewall to limit access of information and reports provided to Eleven by the Roche Group under Article 8 and Article 13 (collectively " **Sensitive Information** ") to (1) such Eleven and Change of Control Group personnel, attorneys, agents and advisors that reasonably need access to and knowledge of such Sensitive Information to perform Eleven's obligations and exercise Eleven's rights under the Agreement and (2) C-level personnel of Eleven or the Change of Control Group, with the objective to prohibit the use of such Sensitive Information by Eleven or the Change of Control Group for competitive reasons that would be detrimental to Roche's interests under the Agreement or Licensed Compounds or Licensed Products without foreclosing the ability of Eleven or the Change of Control Group to perform Eleven's obligations and exercise Eleven's rights under the Agreement. For clarity, (i) information about payments made by Roche under this Agreement shall not be deemed as Sensitive Information that is subject to the firewall of this Section 21.4(c), and (ii) the exceptions under Sections 1.21(i)-(v), 17.3 and 17.4 to Eleven's obligations to protect Roche's Confidential Information shall also apply to Sensitive Information.

21.5 Debarment

Eleven represents and warrants that, as of the Signature Date, it has never been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event Eleven receives notice of its debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, Eleven shall immediately notify Roche in writing and Roche shall have the right, but not the obligation, to terminate this Agreement, effective, at Roche's option, immediately or at a specified future date.

21.6 Independent Contractor

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship to the other Party under this Agreement shall be that of independent contractor, and nothing contained

in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

21.7 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e., the Parties would presumably have concluded this Agreement without the unenforceable provisions.

21.8 Waiver

The failure by either Party to require strict performance or observance of any obligation, term, provision or condition under this Agreement will neither constitute a waiver thereof nor affect in any way the right of the respective Party to require such performance or observance. The waiver by either Party of a breach of any obligation, term, provision or condition hereunder shall not constitute a waiver of any subsequent breach thereof or of any other obligation, term, provision or condition.

21.9 Appendices

All Appendices to this Agreement shall form an integral part to this Agreement.

21.10 Entire Understanding

This Agreement, together with the Exclusivity Agreement, the MTA and the Non-Disclosure Agreement by and between Eleven and Roche US effective June, 2015 (the " **NDA** "), contains the entire understanding between the Parties with respect to the subject matter hereof and supersedes any and all prior agreements, understandings and arrangements, whether written or oral. For clarity, after the Effective Date, the treatment of Information related to Technology (as such terms are defined in the NDA) or Eleven's business or financial information received by Roche or any of its Affiliates from Eleven under the NDA (the " **Eleven NDA Information** "), and any Confidential Information (as such term is defined in the MTA) of Eleven subject to the MTA (the " **Eleven MTA Information** "), is superseded by the licenses and treatment of Confidential Information under this Agreement. For clarity, the three-way confidentiality agreements among (i) Eleven, Roche US and Symbiosis, effective January 25, 2016, (ii) Eleven, Roche US and FujiFilm, effective January 25, 2016, and (iii) Eleven, Roche US and BioAgilytix Labs, LLC, effective June 3, 2016, shall remain in effect.

21.11 Amendments

No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

21.12 Invoices

All invoices that are required or permitted hereunder shall be in writing and sent by Eleven to Roche at the following address or such other US address as Roche may later provide, and referencing the name and date of this Agreement:

Hoffmann-La Roche Inc.
Suite 8
150 Clove Road
Little Falls, NJ 07424
Attn: Roche Partnering Legal Department

With copies to: vfspecialhandling@gene.com

and to: F. Hoffmann-La Roche Ltd
Kreditorenbuchhaltung
Grenzacherstrasse 124
4070 Basel
Switzerland
Attn: (name of a Roche contact at time of invoice, e.g. the Alliance Director)

21.13 Notice

All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Eleven, to: Eleven Biotherapeutics, Inc.
215 First Street, Suite 400
Cambridge, Massachusetts 02142
U.S.A.
Attn: Chief Executive Officer
Facsimile: +1 617-858-0911

if to Roche, to: F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel
Switzerland
Attn: Legal Department
Facsimile No.: +41 61 688 13 96

and: Hoffmann-La Roche Inc.
150 Clove Road
Suite 8
Little Falls, New Jersey 07424
U.S.A.
Attn. Corporate Secretary
Facsimile No.: +1 973 890-8433

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith.

21.14 Interpretation

a) Each Party acknowledges that it has been advised by counsel during the course of negotiation of this Agreement, and, therefore, that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted.
b) The headings, captions and table of contents in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.
c) In construing this Agreement, except where the context acquires otherwise, (i) use of the singular includes the plural and vice versa; (ii) the words “include” “including”, “includes” and “e.g.” means “including without limitation”; (iii) the word “or” is used in the inclusive sense that is typically associated with the phrase “and/or”; (iv) the words “herein,” “hereof” and “hereunder,” and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (v) the verb “will” shall be construed to have the same meaning and effect as the word “shall”; (vi) use of any gender includes any other gender; (vii) any reference to any law or regulation includes any amendment or modification to such law or regulation and shall be deemed also to refer to all rules and regulations promulgated thereunder; (viii) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; and (ix) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Signature Date.

Eleven Biotherapeutics, Inc.

___ /s/ Abbie Celniker_____

Name: Abbie Celniker

Title: Chief Executive Officer

F. Hoffmann-La Roche Ltd

/s/ Stefan Arnold_____

Name: Stefan Arnold

Title: Head Legal Pharma

/s/ Vikas Kabra_____

Name: Vikas Kabra

Title: Head of Transaction Excellence

Hoffmann-La Roche Inc.

___ /s/ John P. Parise_____

Name: John P. Parise

Title: Authorized Signatory

Appendix 1.30

Core Patent Rights

[**]			
Country	**Application No.**	**Status**	**Filing Date**
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

[**]			
Country	**Application No.**	**Status**	**Filing Date**
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

[**]			
Country	**Application No.**	**Status**	**Filing Date**
[**]	[**]	[**]	[**]

Any patents issuing on such patent applications listed above, and further including any patents and patent applications claiming priority from the patents and patent applications listed above and any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

Appendix 1.32
Sequence of Eleven Compounds

Description	Sequence
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

Appendix 1.85

Excluded Roche Patent Rights

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**]

Appendix 6.1

Product Inventory

The following is a complete list the Inventory (other than intermediates, raw materials and in-process research material) and Eleven Cell Line Materials under the Control of Eleven as of the Signature Date, including where and under which conditions each item is stored:

Item	Description	Amounts, format and storage place
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

Appendix 6.2

Agreements with Third Parties

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

Appendix 13.2

Select Non-Prosecution Patent Rights

[**]			
Country	**Application No.**	**Status**	**Filing Date**
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

Any patents issuing on such patent applications listed above, and further including any patents and patent applications claiming priority from the patents and patent applications listed above and any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.

Appendix 17.3

Form of Press Releases

[*pages follow*]

Eleven Biotherapeutics Announces Signing of Exclusive License Agreement

License to Roche Covers IL-6 Antagonist Antibody Technology, Including EBI-031

IND Submission [Announced Today/Planned for this Quarter]

Cambridge, MA – June [13], 2016 –Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced that it has entered into an exclusive license agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (Roche) relating to Eleven's Interleukin-6 (IL-6) technology. Under the terms of the agreement, Eleven has agreed to grant an exclusive, worldwide license to Roche to develop and commercialize EBI-031, a humanized monoclonal antibody that potently binds IL-6 and inhibits all known forms of IL-6 cytokine signaling, currently being developed for the potential treatment of ocular diseases, and all other IL-6 antagonist antibody technology owned by Eleven.

Under the agreement, Eleven will be entitled to an upfront payment of $7.5 million, along with potential future milestone payments of up to $262.5 million. The first potential future milestone payment is subject to the effectiveness of an investigational new drug application (IND) for EBI-031. This first milestone payment will equal $22.5 million if the IND becomes effective on or before September 15, 2016 or $20.0 million if the IND becomes effective after September 15, 2016. In addition, Eleven could be entitled to receive royalties for net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds. Effectiveness of the license agreement is subject to approval of the license by holders of at least a majority of the outstanding shares of Eleven's common stock.

"We remain on track to make a planned submission of an IND for EBI-031 this quarter/were pleased to announce submission of an IND for EBI-031 [today]," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics. "We are pleased to see Roche poised to further develop this potent IL-6 blocker for the potential benefit of patients. As previously announced, we also continue to evaluate additional strategic alternatives with a goal to maximize shareholder value."

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME, and uveitis. EBI-031 was designed and engineered for intravitreal delivery using Eleven's AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R). [Eleven is undertaking the necessary manufacturing development work and nonclinical safety studies to support the submission of an investigational new drug application, or IND, to the FDA in the [first half of 2016] for the purpose of conducting clinical trials of EBI-031 in DME and uveitis.]

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a preclinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the role of cytokines in diseases of the eye, the Company's understanding of the structural biology of cytokines and the Company's ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. For more information please refer to the Company's website www.elevenbio.com .

Important Information

The Company plans to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with the transactions contemplated by the license agreement. Additionally, the Company will file other relevant materials with the SEC in connection with the transactions contemplated by the license agreement. The proxy statement will contain important information about the Company, the transactions contemplated by the license agreement and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available before making any voting or investment decision with respect to the proposed transactions because they will contain important information about the proposed transactions.

Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov . In addition, investors and security holders will be able to obtain free copies of the proxy statement from public company by contacting Leah Monteiro at (617) 714-0619.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement. Information regarding the Company's directors and executive officers is contained in the Company's Form 10-K for the fiscal year ended December 31, 2015, and its proxy statement dated April 29, 2016, each of which has been filed with the SEC. Additional information regarding the participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential effectiveness of the license agreement or receipt of payments thereunder, the future rights and obligations of the parties under the license agreement, the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the review of its strategic alternatives and the outcome of such review, the completion and results of potential strategic transactions, the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and

similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the occurrence of any event, change or other circumstances that could give rise to the termination of the license agreement, the outcome of any legal proceedings that could be instituted against the Company or its directors related to the license agreement, the inability to consummate the transactions contemplated by the license agreement due to the failure to obtain the requisite approval of the Company's stockholders, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contacts:
Leah Monteiro
Eleven Biotherapeutics
Leah.Monteiro@elevenbio.com
617-714-0619

Eleven Biotherapeutics Announces Investigational New Drug Application Submission to Initiate Clinical Trials of EBI-031 for Ocular Diseases

Cambridge, MA – June [13], 2016 – Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial of EBI-031, a humanized monoclonal antibody that potently binds interleukin-6 (IL-6) and inhibits all known forms of IL-6 cytokine signaling, which may be effective for the treatment of ocular diseases such as diabetic macular edema and uveitis.

[Today/On June XX, 2016] Eleven announced that it had entered into an exclusive license agreement with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (Roche) for the further development and commercialization of EBI-031 and all other IL-6 antagonist antibody technology owned by Eleven. Under the terms of the agreement, Eleven could receive up to $262.5 million upon the achievement of certain regulatory, development and commercialization milestones. The first potential future milestone payment is subject to the effectiveness of the IND for EBI-031. This first milestone payment will equal $22.5 million if the IND becomes effective on or before September 15, 2016 or $20.0 million if the IND becomes effective after September 15, 2016. In addition, Eleven could be entitled to receive royalties for net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds. Effectiveness of the license agreement is subject to approval of the license by holders of at least a majority of the outstanding shares of Eleven's common stock.]

"We are pleased to have this IND under review by the FDA," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics. ["We look forward to providing additional details on the development of EBI-031 as a potential treatment for ocular diseases of the eye, such as diabetic macular edema and uveitis, as they become available."]

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME, and uveitis. EBI-031 was designed and engineered for intravitreal delivery using Eleven's AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R).

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a preclinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the role of cytokines in diseases of the eye, the Company's understanding of the structural biology of cytokines and the Company's ability to rationally design and engineer proteins to modulate the

effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. For more information please refer to the Company's website www.elevenbio.com .

[Important Information

The Company plans to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with the transactions contemplated by the license agreement. Additionally, the Company will file other relevant materials with the SEC in connection with the transactions contemplated by the license agreement. The proxy statement will contain important information about the Company, the transactions contemplated by the license agreement and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available before making any voting or investment decision with respect to the proposed transactions because they will contain important information about the proposed transactions.

Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov . In addition, investors and security holders will be able to obtain free copies of the proxy statement from public company by contacting Leah Monteiro at (617) 714-0619.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement. Information regarding the Company's directors and executive officers is contained in the Company's Form 10-K for the fiscal year ended December 31, 2015, and its proxy statement dated April 29, 2016, each of which has been filed with the SEC. Additional information regarding the participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.]

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the [potential effectiveness of the license agreement or receipt of payments thereunder, the future rights and obligations of the parties under the license agreement, the] Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the review of its strategic alternatives and the outcome of such review, the completion and results of potential strategic transactions, the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: [the occurrence of any event, change or other circumstances that could give rise to the termination of the license agreement, the outcome of any legal proceedings that could be instituted against the

Company or its directors related to the license agreement, the inability to consummate the transactions contemplated by the license agreement due to the failure to obtain the requisite approval of the Company's stockholders,] the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:

Leah Monteiro
Eleven Biotherapeutics
Leah.Monteiro@elevenbio.com
617-714-0619

Eleven Biotherapeutics Announces Effectiveness of Investigational New Drug Application for EBI-031

Eleven entitled to receive [$22.5] million milestone payment for IND effectiveness

Cambridge, MA – July XX, 2016 – Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced that the company's Investigational New Drug (IND) application for EBI-031, a humanized monoclonal antibody that potently binds interleukin-6 (IL-6) and inhibits all known forms of IL-6 cytokine signaling, for treatment of ocular diseases, has become effective. As a result of the achievement of this milestone, Eleven is entitled to receive a [$22.5] million payment from F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (Roche) pursuant to the terms of its license agreement with Roche.

On June [13], 2016, Eleven announced that it had entered into an exclusive license agreement with Roche for the further development and commercialization of EBI-031 and all other IL-6 antagonist antibody technology owned by Eleven. Under the terms of the agreement, Eleven could receive up to $262.5 million upon the achievement of certain regulatory, development and commercialization milestones, including this $22.5 million payment upon the effectiveness of the IND for EBI-031. In addition, Eleven could be entitled to receive royalties for net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds. [Effectiveness of the license agreement, including Roche's obligation to make the $22.5 million milestone payment, is subject to approval of the license by holders of at least a majority of the outstanding shares of Eleven's common stock. OR The license agreement became effective on XX 2016 subsequent to the approval of the license by a majority vote of the holders of the outstanding shares of Eleven's common stock.]

"We look forward to Roche advancing EBI-031 into the clinic to explore its potential use for ocular diseases, such as diabetic macular edema, in an effort to bring this potential treatment to patients," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics.

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME, and uveitis. EBI-031 was designed and engineered for intravitreal delivery using Eleven's AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R). Eleven filed an IND with the FDA in June 2016 for the purpose of conducting clinical trials of EBI-031 in DME and uveitis.

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a preclinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the

role of cytokines in diseases of the eye, the Company's understanding of the structural biology of cytokines and the Company's ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. For more information please refer to the Company's website www.elevenbio.com .

Important Information

The Company plans to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with the transactions contemplated by the license agreement. Additionally, the Company will file other relevant materials with the SEC in connection with the transactions contemplated by the license agreement. The proxy statement will contain important information about the Company, the transactions contemplated by the license agreement and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available before making any voting or investment decision with respect to the proposed transactions because they will contain important information about the proposed transactions.

Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov . In addition, investors and security holders will be able to obtain free copies of the proxy statement from public company by contacting Leah Monteiro at (617) 714-0619.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement. Information regarding the Company's directors and executive officers is contained in the Company's Form 10-K for the fiscal year ended December 31, 2015, and its proxy statement dated April 29, 2016, each of which has been filed with the SEC. Additional information regarding the participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential effectiveness of the license agreement or receipt of payments thereunder, the future rights and obligations of the parties under the license agreement, the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the review of its strategic alternatives and the outcome of such review, the completion and results of potential strategic transactions, the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the

occurrence of any event, change or other circumstances that could give rise to the termination of the license agreement, the outcome of any legal proceedings that could be instituted against the Company or its directors related to the license agreement, the inability to consummate the transactions contemplated by the license agreement due to the failure to obtain the requisite approval of the Company's stockholders, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:
Leah Monteiro
Eleven Biotherapeutics
Leah.Monteiro@elevenbio.com
617-714-0619

Eleven Biotherapeutics Announces Effectiveness of Investigational New Drug Application for EBI-031

Eleven entitled to receive $20 million milestone payment for IND effectiveness

Cambridge, MA – Month/Day TBD, 2016 – Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced that the company's Investigational New Drug (IND) application for EBI-031, a humanized monoclonal antibody that potently binds interleukin-6 (IL-6) and inhibits all known forms of IL-6 cytokine signaling, for treatment of ocular diseases, has become effective. As a result of the achievement of this milestone, Eleven is entitled to receive a $20 million payment from F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (Roche) pursuant to the terms of its license agreement with Roche.

On June [13], 2016, Eleven announced that it had entered into an exclusive license agreement with Roche for the further development and commercialization of EBI-031 and all other IL-6 antagonist antibody technology owned by Eleven . [The license agreement became effective on XX, 2016 following the approval of the transaction by a majority vote of holders of the outstanding shares of Eleven's common stock.] Under the terms of the agreement, Eleven could receive up to $260 million upon the achiev ement of certain regulatory, development and commercialization milestones, including this $20 million payment upon the effectiveness of the IND for EBI-031. In addition, Eleven could be entitled to receive royalties for net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds. [Effectiveness of the license agreement, including Roche's obligation to make the $20 million milestone payment, is subject to approval of the license by holders of at least a majority of the outstanding shares of Eleven's common stock]

"We look forward to Roche advancing EBI-031 into the clinic to explore its potential use for ocular diseases, such as diabetic macular edema, in an effort to bring this potential treatment to patients," said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics.

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME, and uveitis. EBI-031 was designed and engineered for intravitreal delivery using Eleven's AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R). Eleven filed an IND with the FDA in June 2016 for the purpose of conducting clinical trials of EBI-031 in DME and uveitis.

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a preclinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the

role of cytokines in diseases of the eye, the Company's understanding of the structural biology of cytokines and the Company's ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. For more information please refer to the Company's website www.elevenbio.com .

Important Information

The Company plans to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with the transactions contemplated by the license agreement. Additionally, the Company will file other relevant materials with the SEC in connection with the transactions contemplated by the license agreement. The proxy statement will contain important information about the Company, the transactions contemplated by the license agreement and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available before making any voting or investment decision with respect to the proposed transactions because they will contain important information about the proposed transactions.

Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov . In addition, investors and security holders will be able to obtain free copies of the proxy statement from public company by contacting Leah Monteiro at (617) 714-0619.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement. Information regarding the Company's directors and executive officers is contained in the Company's Form 10-K for the fiscal year ended December 31, 2015, and its proxy statement dated April 29, 2016, each of which has been filed with the SEC. Additional information regarding the participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential effectiveness of the license agreement or receipt of payments thereunder, the future rights and obligations of the parties under the license agreement, the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the review of its strategic alternatives and the outcome of such review, the completion and results of potential strategic transactions, the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the

occurrence of any event, change or other circumstances that could give rise to the termination of the license agreement, the outcome of any legal proceedings that could be instituted against the Company or its directors related to the license agreement, the inability to consummate the transactions contemplated by the license agreement due to the failure to obtain the requisite approval of the Company's stockholders, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:
Leah Monteiro
Eleven Biotherapeutics
Leah.Monteiro@elevenbio.com
617-714-0619

Eleven Biotherapeutics Completes Exclusive Licensing Deal for IL-6 Antagonist Antibody Technology, Including EBI-031

Eleven entitled to $[7.5][30] million payment

Cambridge, MA – July XX, 2016 – Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a biopharmaceutical company discovering and developing protein therapeutics to treat diseases of the eye, today announced the effectiveness of the exclusive licensing deal with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (Roche), pursuant to which Eleven has granted Roche an exclusive, worldwide license to develop and commercialize EBI-031, a humanized monoclonal antibody that potently binds interleukin-6 (IL-6) and inhibits all known forms of IL-6 cytokine signaling, currently being developed for the treatment of ocular diseases, and all other IL-6 antagonist antibody technology owned by Eleven. In connection with the effectiveness of the license agreement, Eleven is entitled to an upfront payment of $7.5 million.

[On June XX, 2016 Eleven Biotherapeutics announced submission of an investigational new drug application (IND) for EBI-031 to the FDA and is awaiting clearance. Upon effectiveness of the IND, Eleven will be entitled to an additional $22.5 million if the IND becomes effective on or before September 15, 2016 or $20.0 million if the IND becomes effective after September 15, 2016.] OR [On July [XX], 2016, the Investigational New Drug (IND) application for EBI-031 became effective. As a result of the achievement of this milestone, Eleven is entitled to receive an additional $22.5 million payment from Roche pursuant to the terms of the license agreement.] Under the terms of the agreement, Eleven could receive up to an additional $240 million upon the achievement of certain future regulatory, development and commercialization milestones. In addition, Eleven could be entitled to receive royalties for net sales of potential future products containing EBI-031 or any other potential future products containing other Eleven IL-6 compounds.

“This is an important milestone in the development of EBI-031 and we look forward to the advancement by Roche of EBI-031 into the clinic to explore its potential use for ocular diseases, such as diabetic macular edema,” said Abbie Celniker, Ph.D., President and Chief Executive Officer of Eleven Biotherapeutics.

About EBI-031

Eleven Biotherapeutics' most advanced preclinical product candidate is EBI-031 for treatment of diabetic macular edema, or DME, and uveitis. EBI-031 was designed and engineered for intravitreal delivery using Eleven’s AMP-Rx platform. EBI-031 is a potent blocker of both free IL-6 and IL-6 complexed to the soluble IL-6 receptor (IL-6R). Eleven filed an IND with the FDA in June 2016 [and received clearance in XXX 2016] for the purpose of conducting clinical trials of EBI-031 in DME and uveitis.

About Eleven Biotherapeutics

Eleven Biotherapeutics, Inc. is a preclinical-stage biopharmaceutical company with a proprietary protein engineering platform, called AMP-Rx, that it applies to the discovery and development of protein therapeutics to treat diseases of the eye. Eleven's therapeutic approach is based on the role of cytokines in diseases of the eye, the Company's understanding of the structural biology of cytokines and the Company's ability to rationally design and engineer proteins to modulate the effects of cytokines. Cytokines are cell signaling molecules found in the body that can have important inflammatory effects. For more information please refer to the Company's website www.elevenbio.com .

Important Information

The Company plans to file with the Securities and Exchange Commission ("SEC") and mail to its stockholders a proxy statement in connection with the transactions contemplated by the license agreement. Additionally, the Company will file other relevant materials with the SEC in connection with the transactions contemplated by the license agreement. The proxy statement will contain important information about the Company, the transactions contemplated by the license agreement and related matters. Investors and security holders are urged to read the proxy statement carefully when it is available before making any voting or investment decision with respect to the proposed transactions because they will contain important information about the proposed transactions.

Investors and security holders will be able to obtain free copies of the proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov . In addition, investors and security holders will be able to obtain free copies of the proxy statement from public company by contacting Leah Monteiro at (617) 714-0619.

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement. Information regarding the Company's directors and executive officers is contained in the Company's Form 10-K for the fiscal year ended December 31, 2015, and its proxy statement dated April 29, 2016, each of which has been filed with the SEC. Additional information regarding the participants in the solicitation of proxies in respect of the transactions contemplated by the license agreement and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the potential effectiveness of the license agreement or receipt of payments thereunder, the future rights and obligations of the parties under the license agreement, the Company's strategy, future operations, advancement or maturation of its product candidates and product pipeline, clinical development of the Company's product candidates, including expectations regarding timing of regulatory submissions and initiation of clinical trials, regulatory requirements for initiation of clinical trials and registration of product candidates, the review of its strategic alternatives and the outcome of such review, [the results of strategic transactions], the sufficiency of its cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute

forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the occurrence of any event, change or other circumstances that could give rise to the termination of the license agreement, the outcome of any legal proceedings that could be instituted against the Company or its directors related to the license agreement, the inability to consummate the transactions contemplated by the license agreement due to the failure to obtain the requisite approval of the Company's stockholders, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, the adequacy of any clinical models, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission and other reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contact:
Leah Monteiro
Eleven Biotherapeutics
Leah.Monteiro@elevenbio.com
617-714-0619

Exhibit 31.1

Rule 13a-14(a) CERTIFICATION

I, Abbie C. Celniker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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.

/s/ Abbie C. Celniker

Abbie C. Celniker

President and Chief Executive Officer

(Principal Executive Officer)

Dated: August 12, 2016

Exhibit 31.2

Rule 13a-14(a) CERTIFICATION

I, John J. McCabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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.

/s/ John J. McCabe

John J. McCabe

Chief Financial Officer

(Principal Financial Officer)

Dated: August 12, 2016

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. §1350

In connection with the Quarterly Report on Form 10-Q of Eleven Biotherapeutics, Inc. (the "Company") for the fiscal quarter ended June 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Abbie C. Celniker

Abbie C. Celniker
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 12, 2016

/s/ John J. McCabe

John J. McCabe
Chief Financial Officer
(Principal Financial Officer)

Dated: August 12, 2016