

**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 March 31, 2018  
or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 001-36297

**Revance Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**77-0551645**

(I.R.S. Employer  
Identification Number)

7555 Gateway Boulevard  
Newark, California 94560  
(510) 742-3400

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 (§ 232.405 of this chapter) 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of April 27, 2018: 36,783,896

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“Revance Therapeutics,” the Revance logos and other trademarks or service marks of Revance appearing in this quarterly report on Form 10-Q are the property of Revance Therapeutics, Inc. This Form 10-Q contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

**PART I. FINANCIAL INFORMATION**

**ITEM 1. Condensed Consolidated Financial Statements**

**REVANCE THERAPEUTICS, INC.**

**Condensed Consolidated Balance Sheets**  
(In thousands, except share and per share amounts)  
(Unaudited)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2018</b>	<b>2017</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 69,212	\$ 282,896
Short-term investments	199,594	—
Prepaid expenses and other current assets	4,612	2,315
Total current assets	273,418	285,211
Property and equipment, net	10,064	9,250
Restricted cash	580	580
Other non-current assets	718	658
<b>TOTAL ASSETS</b>	<b>\$ 284,780</b>	<b>\$ 295,699</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 5,361	\$ 6,805
Accruals and other current liabilities	11,120	12,225
Deferred revenue, current portion	5,532	—
Financing obligations	983	1,872
Total current liabilities	22,996	20,902
Derivative liability associated with Medicis settlement	2,647	2,613
Deferred revenue, net of current portion	19,275	—
Deferred rent	3,221	3,339
<b>TOTAL LIABILITIES</b>	<b>48,139</b>	<b>26,854</b>
Commitments and Contingencies (Note 8)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.001 per share — 95,000,000 shares authorized as of March 31, 2018 and December 31, 2017; 36,742,847 and 36,516,075 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	37	37
Additional paid-in capital	814,084	810,975
Accumulated other comprehensive loss	(276)	—
Accumulated deficit	(577,204)	(542,167)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>236,641</b>	<b>268,845</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 284,780</b>	<b>\$ 295,699</b>

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

## REVANCE THERAPEUTICS, INC.

**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share amounts)  
(Unaudited)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2018</b>	<b>2017</b>
Revenue	\$ 193	\$ 75
Operating expenses:		
Research and development	22,239	19,409
General and administrative	13,616	7,754
Total operating expenses	<u>35,855</u>	<u>27,163</u>
Loss from operations	(35,662)	(27,088)
Interest income	1,022	311
Interest expense	(44)	(193)
Change in fair value of derivative liability associated with Medicis settlement	(34)	(60)
Other expense, net	(319)	(126)
Net loss	<u>(35,037)</u>	<u>(27,156)</u>
Unrealized loss on available for sale securities	(276)	(52)
Comprehensive loss	<u>\$ (35,313)</u>	<u>\$ (27,208)</u>
Basic and Diluted net loss attributable to common stockholders	<u>\$ (35,037)</u>	<u>\$ (27,156)</u>
Basic and Diluted net loss per share attributable to common stockholders (Note 2)	<u>\$ (0.97)</u>	<u>\$ (0.94)</u>
Basic and Diluted weighted-average number of shares used in computing net loss per share attributable to common stockholders	<u>35,950,593</u>	<u>28,808,195</u>

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

## REVANCE THERAPEUTICS, INC.

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (35,037)	\$ (27,156)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	390	357
Amortization of premium (discount) on investment	(255)	194
Change in fair value of derivative liability associated with Medicis settlement	34	60
Stock-based compensation expense	4,158	3,155
Capitalized interest	(16)	—
Effective interest on financing obligations	44	83
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,310)	(1,144)
Other non-current assets	290	69
Accounts payable	(1,269)	1,135
Accruals and other liabilities	(1,980)	2,055
Deferred revenue	24,807	—
<b>Net cash used in operating activities</b>	<b>(11,144)</b>	<b>(21,192)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(1,068)	(296)
Proceeds from maturities of investments	—	7,750
Proceeds from sales of property and equipment	15	—
Purchases of investments	(199,265)	(36,028)
<b>Net cash used in investing activities</b>	<b>(200,318)</b>	<b>(28,574)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock, net of at-the-market offering commissions	—	26,217
Principal payments made on financing obligations	(932)	(944)
Net settlement of restricted stock awards for employee taxes	(1,666)	(277)
Proceeds from the exercise of stock options and employee stock purchase plan	617	210
Payment of offering costs	(241)	(205)
<b>Net cash provided by (used in) financing activities</b>	<b>(2,222)</b>	<b>25,001</b>
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(213,684)	(24,765)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — Beginning of period	283,476	64,082
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — End of period	\$ 69,792	\$ 39,317
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 16	\$ 110
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:</b>		
Property and equipment purchases included in accounts payable and accruals and other current liabilities	\$ 839	\$ 882
Deferred offering costs	\$ 109	\$ 78

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

## REVANCE THERAPEUTICS, INC.

**Notes to Condensed Consolidated Financial Statements****(Unaudited)****1. The Company and Basis of Presentation**

Revance Therapeutics, Inc., or the Company, was incorporated in Delaware on August 10, 1999 under the name Essentia Biosystems, Inc. The Company commenced operations in June 2002 and on April 19, 2005, changed its name to Revance Therapeutics, Inc. The Company is a clinical-stage biotechnology company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. The Company is leveraging its proprietary portfolio of botulinum toxin type A compounds, formulated with its patented and proprietary peptide technology, to address unmet needs in large and growing neuromodulator markets. The Company's proprietary peptide technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical ("topical" or "our topical product candidate"). The Company is pursuing clinical development for RT002 injectable in a broad spectrum of aesthetic and therapeutic indications and is planning to conduct preclinical development of its topical product candidate. The Company holds worldwide rights for all indications of RT002 injectable and the pharmaceutical uses of its proprietary peptide technology.

Since commencing operations in 2002, the Company has devoted substantially all of its efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel and raising capital, and preclinical and clinical development of, and manufacturing development for, RT002 injectable and topical. The Company has never been profitable and has not yet commenced commercial operations.

Since the Company's inception, the Company has incurred losses and negative cash flows from operations. The Company has not generated significant revenue from product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. During the three months ended March 31, 2018, the Company has recorded a net loss of \$35.0 million and used \$11.1 million of cash for operating activities. As of March 31, 2018, the Company had a working capital surplus of \$250.4 million and an accumulated deficit of \$577.2 million. The Company has funded its operations primarily through the issuance and sale of common stock, convertible preferred stock, notes payable, and convertible notes. As of March 31, 2018, the Company had capital resources consisting of cash, cash equivalents, and investments of \$268.8 million. The Company believes that its existing cash, cash equivalents and investments will allow the Company to fund its operating plan through at least the next 12 months following the issuance of this Form 10-Q.

***Basis of Presentation***

The accompanying unaudited Condensed Consolidated Financial Statements, in the opinion of management, include all adjustments which the Company considers necessary for the fair statement of the Condensed Consolidated Balance Sheets at the date of the balance sheets and the Condensed Consolidated Statements of Operations and Comprehensive Loss and Condensed Consolidated Statements of Cash Flows for the interim periods covered. The Condensed Consolidated Balance Sheet for the year ended December 31, 2017 was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or US GAAP. The interim results presented herein are not necessarily indicative of the results of operations that may be expected for the full fiscal year ending December 31, 2018, or any other future period.

The Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission, or SEC, on March 2, 2018.

The Consolidated Financial Statements of the Company include the Company's accounts and those of its wholly-owned subsidiaries, Revance Therapeutics Limited and Revance International Limited, and have been prepared in conformity with accounting principles generally accepted in the United States of America, or US GAAP. The Company operates in one segment.

***Principles of consolidation***

The Consolidated Financial Statements include the accounts of the company and its wholly-owned subsidiaries. All intercompany transactions have been eliminated.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

***At-The-Market Offering***

In March 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2016 ATM Agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen, the Company's sales agent. Sales of common stock through Cowen under the 2016 ATM agreement will be made by means of ordinary brokers' transactions on the NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Cowen. Cowen will sell the common stock from time to time, based upon instructions from the Company. The Company agreed to pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. During the three months ended March 31, 2017, the Company sold 1,272,437 shares of its common stock under the 2016 ATM Agreement at a weighted average price of \$21.24 per share resulting in net proceeds of \$25.7 million, which was comprised of gross proceeds after commissions of \$26.2 million net of offering expenses of \$0.5 million of which \$0.2 million was paid in 2016 and \$0.1 million remained unpaid as of March 31, 2017.

In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. Sales of common stock through Cantor Fitzgerald under the 2018 ATM Agreement will be made by means of ordinary brokers' transactions on the NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Cantor Fitzgerald. Cantor Fitzgerald will sell the common stock from time to time, based upon instructions from the Company. The Company agreed to pay Cantor Fitzgerald a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cantor Fitzgerald under the 2018 ATM Agreement. No sales of common stock have taken place under the 2018 ATM Agreement as of March 31, 2018.

**2. Summary of Significant Accounting Policies**

Significant accounting policies are described in Note 2 to the Consolidated Financial Statements in Item 15 of the Company's Annual Report on Form 10-K for the year ended December 31, 2017. There have been no changes to the Company's significant accounting policies during the three months ended March 31, 2018, except as described below.

***Use of Estimates***

The preparation of Condensed Consolidated Financial Statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Such management estimates include revenue recognition, accruals, stock-based compensation, the fair value of a derivative liability, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and on assumptions that it believes are reasonable, however, actual results could significantly differ from those estimates.

***Revenue***

Effective January 1, 2018, the Company adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606) using the full retrospective transition method. The Company evaluated its prior contractual revenue arrangement with Precision Dermatology, Inc., which was acquired by Valeant Pharmaceuticals International Inc., or Valeant, in 2014. After Valeant notified the Company that it intended to terminate the asset purchase and royalty agreement in 2015, the Company continued to receive royalties of \$75,000 each quarter until November 2017 when the Company and Valeant entered into an Asset Transfer Agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. Based on its evaluation, the Company determined that the new guidance had no impact to the revenue recognized prior to January 1, 2018 and, accordingly, had no impact on the accumulated deficit as of January 1, 2018. The Company elected to use certain practical expedients permitted related to adoption (Note 3), and the adoption of ASC 606 had no impact on the Company's financial position, results of operations or liquidity. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases,

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

## (Unaudited)

insurance, collaboration arrangements and financial instruments. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

#### Licenses of intellectual property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are determined to not represent distinct performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

#### Milestone payments

At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used, it should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation (as determined to be appropriate) on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

#### Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. As a practical expedient, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.



## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**Net Loss per Share Attributable to Common Stockholders**

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, which includes vested restricted stock awards. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. The diluted net loss per share attributable to common stockholders also includes vested restricted stock awards and, if the effect is not anti-dilutive, unvested restricted stock awards. For purposes of this calculation, options to purchase common stock, unvested restricted stock, and common stock warrants are considered common stock equivalents.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	As of March 31,	
	2018	2017
Outstanding common stock options	3,691,797	3,294,040
Outstanding common stock warrants	34,113	61,595
Unvested restricted stock awards	686,523	555,723
Shares expected to be purchased on December 31 under the 2014 ESPP	16,895	15,159

**Recently Adopted Accounting Pronouncements**

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. This standard amends Accounting Standards Codification 740, *Income Taxes (ASC 740)* to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the Tax Reform Act) pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Act enactment date. This standard is effective upon issuance. As described in the footnotes to the Annual Report on Form 10-K, the Company's accounting for the tax effects of enactment of the Tax Reform Act is being assessed; however, in certain cases, as described below, we made a reasonable estimate of the effects on our existing deferred tax balances and valuation allowance. The Company determined that the \$62.9 million recorded in connection with the re-measurement of certain deferred tax assets and liabilities, and corresponding valuation allowance was a provisional amount and a reasonable estimate at December 31, 2017. The Company has not completed the accounting with regard to the tax effects associated with an intra-entity transfer of certain intellectual property rights with the enactment of Tax Reform Act. Our accounting for the intra-entity transfer reflects the utilization of net operating losses on the basis of the laws in effect before the Tax Reform Act. The Company is evaluating the impact under Tax Reform Act on the Company's global business structure. In all aspects, the Company will continue to make and refine calculations as additional analysis is completed. The Company expects to complete the accounting assessment during the one year measurement period provided by SAB 118.

In May 2017, the FASB issued ASU No. 2017-09, *Scope of Modification Accounting (Topic 718)*, which amends the scope of modification accounting for share-based payment arrangements. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The adoption of this standard on January 1, 2018 did not impact the Company's Condensed Consolidated Financial Statements.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes - Intra-Entity Transfers of Assets Other Than Inventory*, which requires entities to recognize income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The amendments in ASU 2016-16 are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within those annual reporting periods and requires a modified retrospective method of adoption. As of January 1, 2018, the Company adopted ASU 2016-16 and determined this standard did not have a financial statement impact on the Company's Condensed Consolidated Financial Statements as the Company has a full valuation allowance.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which sets forth a single, comprehensive revenue recognition model for all contracts with customers to improve comparability. Subsequently, the FASB

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

issued several standards related to ASU 2014-09 (collectively, the “New Revenue Standard”), including the most recent ASU, ASU 2017-14, *Income Statement - Reporting Comprehensive Income (Topic 220)*, and *Revenue Recognition (Topic 605)*, *Revenue from Contracts with Customers (Topic 606)*, which was issued in November 2017. The New Revenue Standard requires revenue recognition to depict the transfer of goods or services to customers in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In addition, the New Revenue Standard requires expanded disclosures. This New Revenue Standard permits the use of either the retrospective or cumulative effect transition method when adopted. As of January 1, 2018, the Company adopted the New Revenue Standard on a retrospective basis and determined there was no material impact to the Company's Condensed Consolidated Financial Statements.

**Recent Accounting Pronouncements**

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, to address specific consequences of the Tax Reform Act. The update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Reform Act. The accounting update is effective January 1, 2019, with early adoption permitted, and is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Reform Act is recognized. The Company is currently evaluating the impact of the new standard on the Company's Condensed Consolidated Financial Statements.

On February 25, 2016, the FASB issued ASU 2016-02 *Leases (Topic 842)* which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases with terms greater than 12 months. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect these lease and revenue recognition standards will have on its Condensed Consolidated Financial Statements; however, the Company anticipates recognizing assets and liabilities arising from any leases that meet the requirements under ASU 2016-02 on the adoption date and including qualitative and quantitative disclosures in the Company's Notes to the Condensed Consolidated Financial Statements.

**3. Collaboration and License Revenue****Agreement Terms**

On February 28, 2018, the Company and Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., entered into a collaboration agreement or the Mylan Collaboration, pursuant to which the Company and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®.

Under the Mylan Collaboration, the Company will be primarily responsible for (a) non-clinical development activities, (b) clinical development activities in North America, and (c) manufacturing and supply of clinical drug substance and drug product; and Mylan will be primarily responsible for (a) clinical development activities outside of North America (excluding Japan) (the “ex-U.S. Mylan territories”), (b) regulatory activities, and (c) commercialization for any approved product. The Company will be solely responsible for an initial portion of non-clinical development costs. The remaining portion of any non-clinical development costs and clinical development costs for obtaining approval in the U.S. and Europe will be shared equally between the parties, and Mylan will be responsible for all other clinical development costs and commercialization expenses. The Company and Mylan will form a joint steering committee, consisting of an equal number of members from the Company and Mylan, to oversee and manage the development, manufacture and commercialization of the biosimilar. The parties will also enter into a separate agreement, within six months, covering supply of drug substance and drug product. In addition, Mylan may elect to have the drug product manufactured by another party, including a third-party contract manufacturing organization or a Mylan affiliate, however may not manufacture or have manufactured the drug substance, rights to which are retained by the Company.

The Company granted Mylan an exclusive, world-wide license (excluding Japan) to the Company's intellectual property rights for the development and commercialization of the biosimilar under the Mylan Collaboration. The Company retained all

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

## (Unaudited)

rights in Japan and has retained rights in the U.S. and ex-U.S. Mylan territories to develop and manufacture the biosimilar for Mylan to commercialize.

Mylan paid the Company a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. The upfront payment does not represent a financing component for the transfer of goods or services. The contingent payments would be payable following Mylan's decision to continue development services for Initial Phase and Phase 3 clinical trials and upon meeting certain milestones. In addition, Mylan will pay the Company royalties on sales of the biosimilar in the Mylan territories. With respect to royalties on sales of the biosimilar in the Mylan territories, Mylan would pay the Company low to mid-double digit royalties on any sales of the biosimilar in the U.S., mid-double digit royalties on any sales in Europe, and high single digit royalties on any sales in other ex-U.S. Mylan territories. However, the Company agreed to waive royalties for U.S. sales, up to a limit of \$50 million in annual sales, during the first approximately four years after commercialization to defray launch costs.

The term of the collaboration will continue, on a country-by-country basis, in perpetuity until terminated by either party pursuant to the terms of the Mylan Collaboration. Either party may terminate the agreement for breach by, or bankruptcy of, the other party. Mylan may terminate the Mylan Collaboration in its entirety or on a region-by-region basis, and may also terminate if a biosimilar development pathway is not deemed viable, with such determination only occurring after an advisory meeting with the U.S. Food and Drug Administration, or FDA. All rights, including licenses, and obligations terminate in the country or countries for which termination applies, with limited exceptions for royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the biosimilar in the country or countries for which termination applies.

**Revenue Recognition**

The Company identified the following material promises within the Agreement: (1) intellectual property license, or IP license, for technology and know-how related to the biosimilar, (2) the performance of initial development services for the biosimilar prior to the FDA advisory meeting, (3) the performance of development services, during the Initial Phase and Phase 3 clinical trials for the biosimilar through the filing of an Investigational New Drug, or IND, application by the Company, and (4) manufacturing services to provide drug substance or drug product during the initial development, development, and commercialization periods. The Company considered that the license has standalone functionality and is capable of being distinct. However, the Company determined that the license is not distinct from the development and manufacturing services within the context of the agreement because the development and manufacturing services significantly increase the utility of the intellectual property.

Specifically, the Company's development, manufacturing and commercialization license can only provide benefit to Mylan in combination with the Company's development services during initial development, the Initial Phase study, and the Phase 3 study. The IP related to the biosimilar platform, which is proprietary to the Company, is the foundation for the development activities related to the treatment for all indications. The manufacturing services are a necessary and integral part of the development services as they could only be conducted utilizing the outcomes of these services. Given the development services under the Mylan Collaboration are expected to involve significant further development of the initial IP, the Company has concluded that the development and compound supply services are not distinct from the license, and thus the license, development services and compound supply services are combined into a single performance obligation. The nature of the combined performance obligation is to provide development and manufacturing services to Mylan under the arrangement.

The Company evaluated whether the Mylan Collaboration contains an option with a material right. The Company determined the Mylan Collaboration contains an option with a material right, because it includes consideration for the IP license, and provides economic value for the duration of the entire development period, defined as the initial development through regulatory approval.

Further, in accordance with ASC 606, the Company elected to use a practical alternative to estimating the standalone fair value selling price of the material right, which is based on the cost of expected services to be provided for the duration of the contract.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

## (Unaudited)

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. The Company estimated the transaction price for the Mylan Collaboration using the most likely amount method. In order to determine the transaction price, the Company evaluated all of the payments to be received during the duration of the contract, which included milestones and consideration payable by Mylan. The transaction price does not include considerations that are constrained or which could potentially require the Company to reverse future revenue. The transaction price of \$81.0 million included the \$25 million upfront payment, \$40 million of development milestones, and estimated variable consideration for cost-sharing payments from Mylan. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. As of March 31, 2018, the transaction price allocated to undelivered performance obligations is \$80.8 million.

The Company estimates revenue recognized and deferred revenue based on the estimated cost of services incurred over the estimated cost of services to be provided for the development period. For the three months ended March 31, 2018, the Company recognized \$0.2 million of revenue related to development services rendered. As of March 31, 2018, the Company recorded short-term and long-term deferred revenue of \$5.5 million and \$19.3 million, respectively. The Company estimates that, if the option is exercised, long-term deferred revenue will be recognized over the Initial Phase and Phase 3 study development period. Nonetheless, it is reasonably possible that our estimated cost of total services to be provided could change.

#### 4. Medicis Settlement

In July 2009, the Company entered into a license agreement with Medicis Pharmaceutical Corporation, or Medicis, granting Medicis worldwide aesthetic and dermatological rights to the Company's investigational botulinum toxin type A product candidates. In October 2012, the Company entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT002 injectable and RT001 topical from Medicis and for consideration payable by the Company to Medicis of up to \$25.0 million, comprised of (i) an upfront payment of \$7.0 million, which was paid in 2012, (ii) a proceeds sharing arrangement payment of \$14.0 million due upon specified capital raising achievements by the Company, of which \$6.9 million was paid in 2013 and \$7.1 million in 2014, and (iii) a Product Approval Payment of \$4.0 million to be paid upon the achievement of regulatory approval for RT002 injectable or RT001 topical by the Company. Medicis was subsequently acquired by Valeant Pharmaceuticals International, Inc. in December 2012.

The Company determined that the settlement provisions related to the proceeds sharing arrangement payment in (ii) above and Product Approval Payment in (iii) above were derivative instruments that require fair value accounting as a liability and periodic fair value remeasurements until settled.

As of March 31, 2018, the Company determined the fair value of its liability for the Product Approval Payment was \$2.6 million, which was measured by assuming a term of 2.25 years, a risk-free rate of 2.30% and a credit risk adjustment of 6.50%. The Company's assumption for the expected term is based on an expected Biologics License Application, or BLA, approval in 2020. The Company did not make any payments under the Product Approval Payment during the three months ended March 31, 2018.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**5. Cash Equivalents and Investments**

The Company's cash equivalents and investments consist of money market funds, U.S. treasury securities, and U.S. government agency obligations, which are classified as available-for-sale securities.

The following table is a summary of amortized cost, unrealized gain and loss, and fair value (in thousands):

	March 31, 2018				December 31, 2017			
	Cost	Gross Unrealized		Fair Value	Cost	Gross Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
Money market funds	\$ 49,096	\$ —	\$ —	\$ 49,096	\$ 236,744	\$ —	\$ —	\$ 236,744
U.S. treasury securities	114,982	—	(161)	114,821	—	—	—	—
U.S. government agency obligations	84,888	—	(115)	84,773	—	—	—	—
Total cash equivalents and available-for-sale securities	<u>\$ 248,966</u>	<u>\$ —</u>	<u>\$ (276)</u>	<u>\$ 248,690</u>	<u>\$ 236,744</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 236,744</u>

Classified as:

Cash equivalents	\$ 49,096	\$ 236,744
Short-term investments	199,594	—
Total cash equivalents and available-for-sale securities	<u>\$ 248,690</u>	<u>\$ 236,744</u>

There have been no significant realized gains or losses on available-for-sale securities for the periods presented. No significant available-for-sale securities held as of March 31, 2018 have been in a continuous unrealized loss position for more than 12 months, and unrealized gains and losses are included in "accumulated other comprehensive loss" within shareholders' equity on the Condensed Consolidated Balance Sheets. As of March 31, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the cost basis of the investment will be recovered. The Company believes it has no other-than-temporary impairments on its securities as it does not intend to sell these securities and does not believe it is more likely than not that it will be required to sell these securities before the recovery of their amortized cost basis. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in fair value. Our cash equivalents and short-term investments are due within one year.

**Related Party Transactions**

Of the Company's total cash, cash equivalents, and short-term investments of \$268.8 million and \$282.9 million as of March 31, 2018 and December 31, 2017, respectively, the Company held cash equivalents and short-term investments with a total fair value of \$126.1 million and \$150.7 million, respectively, in an investment account with a prior related party, J.P. Morgan Securities LLC. As of December 31, 2017, JPMorgan Chase & Co. and its wholly owned subsidiaries JPMorgan Chase Bank, National Association (NA), J.P. Morgan Investment Management Inc., and JPMorgan Asset Management (UK) Limited held 9.75% of the Company's outstanding common stock. J.P. Morgan Securities LLC, who acts as a custodian and trustee for certain Company investments, is an affiliate of JPMorgan Chase Bank, NA. For the three months ended March 31, 2018, J.P. Morgan Securities LLC. held less than 10% of the Company's outstanding common stock and is no longer considered a related party.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**6. Fair Value Measurements**

The Company determines the fair value of certain financial assets and liabilities using three levels of inputs as follows:

- Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 — Valuations based on unobservable inputs to the valuation methodology and including data about assumptions market participants would use in pricing the asset or liability based on the best information available under the circumstances.

The carrying values of cash, prepaid expenses and other current assets, accounts payable, and accruals and other current liabilities approximate fair value due to the short maturities of these instruments.

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The fair value of these instruments was as follows (in thousands):

	As of March 31, 2018			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 49,096	\$ 49,096	\$ —	\$ —
U.S. treasury securities	114,821	114,821	—	—
U.S. government agency obligations	84,773	—	84,773	—
Total assets measured at fair value	\$ 248,690	\$ 163,917	\$ 84,773	\$ —
<b>Liabilities</b>				
Derivative liability associated with Medicis settlement	\$ 2,647	\$ —	\$ —	\$ 2,647
Total liabilities measured at fair value	\$ 2,647	\$ —	\$ —	\$ 2,647
	As of December 31, 2017			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 236,744	\$ 236,744	\$ —	\$ —
Total assets measured at fair value	\$ 236,744	\$ 236,744	\$ —	\$ —
<b>Liabilities</b>				
Derivative liabilities associated with Medicis settlement	\$ 2,613	\$ —	\$ —	\$ 2,613
Total liabilities measured at fair value	\$ 2,613	\$ —	\$ —	\$ 2,613

The fair value of the U.S. government agency obligations is estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. The Company did not transfer any assets or liabilities measured at fair value on a recurring basis between Level 1 and Level 2 during the three months ended March 31, 2018 and the year ended December 31, 2017.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	<b>Derivative Liability Associated with Medicis Settlement</b>
Fair value as of December 31, 2017	\$ 2,613
Change in fair value	34
Fair value as of March 31, 2018	\$ 2,647

The fair value of the derivative liability resulting from the Medicis litigation settlement was determined by estimating the timing and probability of the related regulatory approval and multiplying the payment amount by this probability percentage and a discount factor based primarily on the estimated timing of the payment and a credit risk adjustment (Note 5). Generally, increases or decreases in these unobservable inputs would result in a directionally similar impact to the fair value measurement of this derivative instrument. The significant unobservable inputs used in the fair value measurement of the Product Approval Payment derivative are the expected timing and probability of the payments at the valuation date and the credit risk adjustment.

## 7. Notes Payable and Financing Obligations

### *Essex Capital Notes*

On December 20, 2013, the Company signed a Loan and Lease Agreement (Original Agreement) to borrow up to \$10.8 million in the form of Secured Promissory Notes from Essex Capital, or the Essex Notes, to finance the completion and installation of the Company's RT001 topical commercial fill/finish line, or the Fill/Finish Line. In December 2013 and January 2014, the Company withdrew a total of \$5.0 million under the terms of the Original Agreement. In May 2014, pursuant to the terms of the Original Agreement, the Company sold equipment to Essex Capital, resulting in partial settlement of the outstanding loan balance of \$1.1 million, and leased the equipment back for fixed monthly payments to be paid over 3 years.

On December 17, 2014, the Company entered into the First Amendment to the Loan and Lease Agreement (First Amendment) with Essex Capital. Under the terms of the First Amendment, the Company agreed to repay the outstanding debt balance of \$3.9 million and issued a warrant to purchase 44,753 shares of common stock.

In February 2015, the Company executed the Second Amendment to the Loan and Lease Agreement (Second Amendment), under which the term of the facility was extended to April 15, 2015 and the purchase price for the remainder of the equipment was increased by \$0.1 million to approximately \$9.8 million. Concurrently with this sale, the Company leased the equipment back from Essex Capital for a fixed monthly payment to be paid monthly over 3 years.

None of the leases qualified for sale-leaseback accounting due to the Company's continuing involvement in the equipment. Therefore, the Company accounted for these transactions as financing obligations using the effective interest rate method.

The leases provide for the option to purchase the leased equipment for 10% of the original purchase amount and, in June 2015, the Company exercised its option to purchase the remainder of the equipment sold and leased back from Essex Capital for 10% of the original purchase amount, or approximately \$1.1 million, at the conclusion of the lease terms. In May 2017, the Company paid \$0.1 million to purchase the equipment sold and leased back from Essex Capital in May 2014.

The Company paid principal and interest payments on the Essex Capital Lease of \$0.9 million for the three months ended March 31, 2018. In April 2018, the Company paid \$1.0 million to purchase the remaining equipment sold and leased back, which excludes sales and use taxes paid, from Essex Capital and there are no remaining commitments or liabilities payable to Essex Capital.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**8. Commitments and Contingencies*****Facility Lease***

In January 2010, the Company entered into a non-cancelable facility lease that requires monthly payments through January 2022. This facility is used for research, manufacturing, and administrative functions.

In February 2014, the Company extended the term of the Lease by thirty-six (36) months to January 2025. Under the terms of the lease agreement, the payments escalate over the term of the lease with the exception of a decrease in payments at the beginning of 2022. However, the Company recognizes the expense on a straight-line basis over the life of the lease. Rent expense was \$1.3 million for the three months ended March 31, 2018 and 2017, respectively.

In November 2017, the Company entered into a non-cancelable equipment operating lease that requires sixty (60) equal monthly payments through October 2022. Lease payments total \$0.2 million during the entire lease term.

As of March 31, 2018, the aggregate total future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

<u>Year Ending December 31,</u>		
2018		\$ 4,226
2019		5,812
2020		5,996
2021		6,173
2022 and thereafter		14,512
Total payments		<u>\$ 36,719</u>

***Other Milestone-Based Commitments***

The Company has one remaining future milestone payment to List Laboratories of \$2.0 million due and payable on the achievement of a certain regulatory milestone. The Company is also obligated to pay royalties to List Laboratories on future sales of botulinum toxin products.

The Company has one remaining future milestone payment of \$4.0 million due and payable to Valeant Pharmaceuticals International, Inc., which acquired Medicis in December 2012, upon the achievement of regulatory approval for RT002 injectable or RT001 topical (Note 4).

In June 2016, the Company entered into an asset purchase agreement with Botulinum Toxin Research Associates, Inc., or BTRX (the "BTRX Purchase Agreement"). Under the BTRX Purchase Agreement, the Company acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and was granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX. In exchange, the Company agreed to an upfront expenditure of \$2.0 million of which \$1.8 million was paid immediately, \$0.1 million was paid in June 2017, and the remaining \$0.1 million, which is recorded in accruals and other current liabilities on the Condensed Consolidated Balance Sheet as of March 31, 2018, is payable in June 2018. The Company also has obligations to pay Botulinum Toxin Research Associates, Inc. (BTRX) up to \$16.0 million upon the satisfaction of specified milestones relating to the Company's product revenue, intellectual property, and clinical and regulatory events.

In April 2016, the Company entered into an agreement with BioSentinel, Inc. to in-license their technology and expertise for research and development and manufacturing purposes. In addition to minimum quarterly use fees, the Company has a one-time future milestone payment of \$0.3 million payable to BioSentinel, Inc. upon the achievement of regulatory approval.

The Company accrues for contingencies when it is probable that a loss has been incurred and the amount of loss can be reasonably estimated. The Company expects that contingencies related to regulatory approval milestones will only become probable once such regulatory outcome is achieved.



## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**Purchase Commitments**

On March 14, 2017, the Company entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the “Services Agreement”) and Statement of Work (“SoW”) with Ajinomoto Althea, Inc., a contract development and manufacturing organization (“Althea”). Under the Services Agreement, Althea has agreed, among other things, to provide the Company with a future source of commercial fill/finish services for the Company’s neuromodulator products. The Services Agreement has an initial term that will expire in 2024, unless terminated sooner by either party. In accordance with the Services Agreement, the Company will have minimum purchase obligations based on its production forecasts. As of March 31, 2018, the Company made non-refundable advanced payments of \$1.3 million in accordance with the terms of this arrangement. The remaining services are cancellable at any time, with the Company required to pay costs incurred through the cancellation date.

**Contingencies**

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company is not subject to any known current pending legal matters or claims that would have a material adverse effect on its financial position, results of operations or cash flows.

**Indemnification**

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

No amounts associated with such indemnifications have been recorded during the three months ended March 31, 2018.

**9. Stockholders' Equity****Convertible Preferred Stock**

As of March 31, 2018 and December 31, 2017, the Company had 5,000,000 shares of convertible preferred stock with a par value of \$0.001 per share authorized and no preferred stock issued and outstanding.

**Warrants**

As of March 31, 2018 and December 31, 2017, the Company had outstanding warrants to purchase 34,113 shares of common stock at an exercise price per share of \$14.95.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**Stock Option Plan****2014 Equity Incentive Plan and 2014 Inducement Plan**

On January 1, 2018, the number of shares of common stock reserved for issuance under the Company's 2014 Equity Incentive Plan, or 2014 EIP, automatically increased by 4% of the total number of shares of the Company's common stock outstanding on December 31, 2017, or 1,460,643 shares. During the three months ended March 31, 2018, the Company granted stock options for 635,350 shares of common stock and 222,100 restricted stock awards under the 2014 EIP. As of March 31, 2018, there were 1,655,523 shares available for issuance under the 2014 EIP.

During the three months ended March 31, 2018, there were no stock options or restricted stock awards granted under the 2014 Inducement Plan (the "2014 IN"). As of March 31, 2018, there were 292,096 shares available for issuance under the 2014 IN. The grant-date fair value of the employee stock options under the 2014 EIP and 2014 IN was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2018	2017
Expected term (in years)	6.0	6.0
Expected volatility	60.8%	68.4%
Risk-free interest rate	2.6%	2.1%
Expected dividend rate	—%	—%

*Fair Value of Common Stock.* The fair value of the shares of common stock is based on the Company's stock price as quoted by the NASDAQ.

*Expected Term.* The expected term for employees and non-employee directors is based on the simplified method, as the Company's stock options have the following characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable, or "plain vanilla" options, and the Company has a limited history of exercise data. The expected term for non-employee consultants is based on the remaining contractual term.

*Expected Volatility.* The expected volatility is based on the historical volatility of a group of similar entities combined with the historical volatility of the Company. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, capital structure, and size.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term of the options.

*Expected Dividend Rate.* The Company has not and does not plan to pay dividends in the foreseeable future, and therefore used an expected dividend rate of zero percent in the valuation model.

*Forfeitures.* The Company accounts for forfeitures as they occur.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

During the three months ended March 31, 2018, there were outstanding options and awards issued to non-employee consultants which have continued to vest in accordance with the 2014 EIP. During the three months ended March 31, 2017, there were no outstanding options and awards issued to non-employee consultants. The fair value of the stock options outstanding for non-employee consultants is calculated at each reporting date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2018	2017
Expected term (in years)	8.8 years	N/A
Expected volatility	64.0%	N/A
Risk-free interest rate	2.8%	N/A
Expected dividend rate	—%	N/A

**2014 Employee Stock Purchase Plan**

On January 1, 2018, the number of shares of common stock reserved for issuance under the Company's 2014 Employee Stock Purchase Plan, or 2014 ESPP, automatically increased by the maximum of 300,000 shares. As of March 31, 2018, there were 1,216,834 shares available for issuance under the 2014 ESPP.

The fair value of the option component of the shares purchased under the 2014 ESPP was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended March 31,	
	2018	2017
Expected term (in years)	0.5	0.5
Expected volatility	59.3%	72.4%
Risk-free interest rate	1.6%	0.7%
Expected dividend rate	—%	—%

*Fair Value of Common Stock.* The fair value of the shares of common stock is based on the Company's stock price.

*Expected Term.* The expected term is based on the term of the purchase period under the 2014 ESPP.

*Expected Volatility.* The expected volatility is based on the historical volatility of the Company's common stock.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term.

*Expected Dividend Rate.* The Company has never paid dividends and does not plan to pay dividends in the foreseeable future, and therefore used an expected dividend rate of zero percent in the valuation model.

**Total Stock-Based Compensation**

Total stock-based compensation expense related to options, restricted stock awards, and ESPP for employees, non-employee directors, and non-employee consultants was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 1,923	\$ 1,304
General and administrative	2,235	1,851
Total stock-based compensation expense	\$ 4,158	\$ 3,155

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

**10. Subsequent Events**

In April 2018, the Company entered into an agreement with a broker to sell certain topical fill/finish line equipment to a third party buyer (the "Buyer") for a purchase price of \$1.2 million. The Company is currently evaluating the impact of this transaction on the Company's Condensed Consolidated Financial Statements.

## 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 Condensed Consolidated Financial Statements and the accompanying notes appearing elsewhere in this Quarterly Report on this Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings, including our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 2, 2018. The words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. The following discussion and analysis contains forward-looking statements within meaning of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the results, timing and completion of our clinical trials and regulatory submissions needed for the approval of RT002 injectable for the treatment of glabellar (frown) lines, muscle movement disorders, including cervical dystonia, and plantar fasciitis, in the United States, Europe and other countries;
- our expectations regarding our future development of RT002 injectable and our topical product candidate for other indications, including upper limb spasticity and chronic migraine;
- our expectations regarding the development of future product candidates;
- the potential for commercialization by us of RT002 injectable, if approved;
- our expectations regarding the potential market size, opportunity and growth potential for RT002 injectable and our topical product candidate, if approved for commercial use;
- our belief that RT002 injectable and our topical product candidate can expand overall demand for botulinum toxin;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners including distributors, to commercialize our product candidates, if approved;
- our ability to manufacture in our facility and to scale up our manufacturing capabilities and those of future third-party manufacturers if our product candidates are approved;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model, and strategic plans for our business, product candidates and technology;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to establish collaborations or obtain additional funding;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;
- our financial performance, including future revenue targets; and
- developments and projections relating to our competitors and our industry.

*These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in “Risk Factors” included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is neither possible for management to predict all risks nor assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.*

## Overview

Revanche Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development, manufacturing, and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. We are leveraging our proprietary portfolio of botulinum toxin type A compounds, formulated with our patented and proprietary peptide technology, to address unmet needs in large and growing neuromodulator markets. Our proprietary peptide technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical (“topical” or “our topical product candidate”). We are pursuing clinical development for RT002 injectable and planning to conduct additional preclinical development for topical. Neither formulation of our product candidates contains albumin or any other animal or human-derived materials. We believe this reduces the risk of the transmission of certain viral diseases. We hold worldwide rights for all indications of RT002 injectable and topical, and the pharmaceutical rights to our proprietary peptide technology.

### ***DaxibotulinumtoxinA for Injection (RT002 or RT002 Injectable)***

RT002 injectable is a novel, injectable formulation of botulinum toxin type A designed to be a targeted and long-acting treatment. We believe RT002 injectable may provide delivery of botulinum toxin to intended treatment sites, while potentially reducing the unwanted spread of botulinum toxin to adjacent areas. We believe, and our preclinical and clinical studies indicate, that this delivery, enabled by our proprietary peptide technology, may result in high response rates and long duration of effect. We are studying RT002 injectable for aesthetic indications, such as glabellar (frown) lines and therapeutic indications, such as cervical dystonia and plantar fasciitis. We believe RT002 injectable has the potential to expand into additional aesthetic and therapeutic indications in the future.

#### *Glabellar Lines*

Glabellar, or frown lines, are the result of the gathering of the tissue between the eyebrows into a fold. They are caused by the repeated action of underlying muscles associated with facial expression. Years of squinting and frowning tend to leave deep wrinkles in the skin between the eyebrows and on the bridge of the nose, across the forehead and at the corners of the eyes. On many people, frown lines produce an angry or sad look that detracts from a pleasant facial appearance. Physical, emotional and social reasons for treating frown lines and forehead furrows include improved appearance and enhanced self-esteem.

We are in Phase 3 clinical development for RT002 injectable for the treatment of glabellar lines. In December 2017, we announced top-line results for the SAKURA 1 and SAKURA 2 pivotal trials.

Both SAKURA 1 and SAKURA 2 met the primary composite endpoint by delivering highly statistically significant improvement against placebo in reducing the severity of glabellar lines. The percentage of RT002-treated patients who had none or mild wrinkles and achieved at least a two-point improvement from baseline on both validated physician and patient assessments was 73.6 percent in SAKURA 1 and 74.0 percent in SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 4. Also, at that time point, 88 percent of RT002-treated patients in SAKURA 1 and 91 percent of RT002 patients in SAKURA 2 said they were very satisfied or satisfied with their treatment experience.

There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on

both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS. The percentage of RT002-treated patients who achieved a none or mild response on IGA-FWS was 35.3 percent in SAKURA 1 and 29.4 percent at SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 24. The median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 24.0 weeks for SAKURA 1 and 23.9 weeks for SAKURA 2. The median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 27.7 weeks for SAKURA 1 and 26.0 weeks for SAKURA 2. For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study. This endpoint, was the median duration of greater or equal to 1 point improvement from baseline on IGA-FWS for RT002-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.

In addition to SAKURA 1 and SAKURA 2, the SAKURA Phase 3 program includes a long-term, open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety of RT002 injectable for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. In the fourth quarter of 2017, we completed enrollment of more than 2,500 subjects at 66 sites in the U.S. and Canada for SAKURA 3. Depending on the number of treatments and duration of follow-up, a subject may be on trial for a maximum of 86 weeks. We have designed SAKURA 3 to support a safety database adequate for both domestic and international marketing applications. Assuming successful completion of our SAKURA Phase 3 program in the second half of 2018, we plan to file marketing applications first in the United States in the first half of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries. If approved, we believe RT002 injectable has the potential to address significant unmet needs in these geographies.

In October 2015, we reported results from BELMONT, a Phase 2 active comparator, placebo-controlled clinical trial for the treatment of glabellar lines against BOTOX® Cosmetic. The 24-week data, which we reported in October 2015, showed that RT002 injectable achieved its primary efficacy measurement at four weeks for all doses of RT002 injectable and that such efficacy was highly statistically significant as compared to placebo. In addition, the 40 Unit dose of RT002 injectable demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 injectable appeared to be generally safe and well-tolerated.

### *Cervical Dystonia*

We have also been developing RT002 for the treatment of cervical dystonia, a muscle movement disorder. Muscle movement disorders, such as cervical dystonia, are neurological conditions that affect a person's ability to control muscle activity in one or more areas of the body. In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable to evaluate the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia.

In May 2017, we announced positive 24 week topline results in all three cohorts from the Phase 2 trial. The topline data demonstrated a median duration of at least 24 weeks for each of the three cohorts. The topline data also displayed a clinically significant impact on cervical dystonia signs and symptoms. At Week 4, RT002 injectable showed a clinically significant mean reduction of 38% from baseline across all three cohorts. This reduction continued to increase to 50% at Week 6 for all subjects, was 42% at Week 12 and was maintained at or above 30% through Week 24. The topline data also showed that RT002 injectable appeared to be generally safe and well-tolerated through Week 24 in all three cohorts. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were generally transient and mild to moderate in severity, with one case of neck pain reported as severe. The most common adverse events were dysphagia, or difficulty in swallowing (14%), of which all cases were mild in severity, injection site redness (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%) and muscle weakness (5%).

In November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we plan to initiate our Phase 3 program for cervical dystonia in the second quarter of 2018. The Phase 3 Program is expected to include a single pivotal trial and an open-label safety study. In November 2017, the FDA also granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

### *Plantar Fasciitis*

We are also developing RT002 for the treatment of plantar fasciitis. Plantar fasciitis is a painful affliction caused by inflammation of the ligament running along the bottom of the foot and is the most common cause of heel pain for patients who visit podiatrists and orthopedic foot and ankle surgeons. In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study is evaluating the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. In April 2017, we expanded our plantar fasciitis Phase 2 program from a single-site study to a multi-center study with protocol updates. The primary efficacy endpoint is the reduction in the visual analog scale (VAS) for pain in the foot at eight weeks and subjects will be followed for 16 weeks following treatment. In January 2018, we announced the interim 8-week Phase 2a results for the plantar fasciitis trial. The trial's primary endpoint, the reduction in the patient-reported visual analog scale (VAS) for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with RT002. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with RT002, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the control group at three of the five study sites. While the results are not statistically significant ( $p=0.39$ ), RT002 provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. RT002 appeared to be generally safe and well-tolerated through Week 8. The majority of adverse events in both treatment groups were mild in severity. There were no treatment-related serious adverse events. The most common treatment-related adverse events for RT002 and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant. We plan to conduct another Phase 2, double-blind, placebo-controlled trial utilizing two doses of RT002 in the second half of 2018.

### *Other indications*

In April 2018, we announced two new clinical programs for RT002: adult upper limb spasticity and chronic migraine. We plan to initiate a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018. We also plan to initiate a Phase 2 study to treat chronic migraine in 2019.

### ***DaxibotulinumtoxinA Topical***

Our topical product candidate presents several potential advantages, including painless topical administration, no bruising, ease of use and limited dependence on administration technique by physicians and medical staff. We believe these potential advantages may improve the experience of patients undergoing botulinum toxin procedures and could make our topical product candidate suitable for multiple indications in the future.

We discontinued clinical development of our topical product candidate in 2016 and are planning to conduct additional preclinical work for topical in therapeutic and aesthetic applications where botulinum toxin has shown efficacy and is particularly well suited for injection-free treatments.

### ***OnabotulinumtoxinA biosimilar***

On February 28, 2018, we entered into a collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. As part of the agreement Mylan agreed to pay a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million.

Since commencing operations in 2002, we have devoted substantially all our efforts to identifying and developing our product candidates for the aesthetic and therapeutic indications, recruiting personnel, raising capital, and preclinical and clinical development of, and manufacturing capabilities for, RT002 injectable and our topical product candidate. We have retained all worldwide rights to develop and commercialize RT002 injectable and our topical product candidate. We have not filed for



approval with the FDA for the commercialization of RT002 injectable or our topical product candidate to treat any indication, and we have not generated any revenue from product sales for RT002 injectable or our topical product candidate.

## Results of Operations

### Revenue

The following table presents our revenue for the periods indicated and related changes from the prior period.

	Three Months Ended March 31,		
	2018	2017	Change
	(In thousands, except percentages)		
Milestone	\$ 193	\$ —	100%
Relastin Royalty	—	75	(100)%
Total revenue	<u>\$ 193</u>	<u>\$ 75</u>	157%

Our total revenue for the three months ended March 31, 2018 increased, compared to the same period in 2017, primarily due to revenue recognized from the collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (“Mylan”). On February 28, 2018, we entered into a collaboration and license agreement (the “Agreement”) with Mylan pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. As part of the Agreement Mylan paid us a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million.

We recognized royalty revenue during the three months ended March 31, 2017 related to the Relastin asset purchase and royalty agreement. In August 2011, we entered into the Relastin asset purchase and royalty agreement to sell the business related to our Relastin product line, to Precision Dermatology, Inc., or PDI. The Relastin asset purchase and royalty agreement provided for a minimum royalty payment of \$0.3 million per year, to be paid quarterly for up to 15 years from the execution date. PDI was subsequently acquired by Valeant Pharmaceuticals International, Inc., or Valeant, in July 2014. On April 23, 2015, we received notice from Valeant terminating the asset purchase and royalty agreement effective as of July 23, 2015. The Company was entitled to the minimum royalty payment until Valeant returns the Relastin® intellectual property rights to the Company. In November 2017, Revance and Valeant entered into an Asset Transfer Agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. The Company does not have any current plans for future development of Relastin® and its focus is primarily on the development of RT002 injectable.

### Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses. The largest component of our operating expenses is our personnel costs including stock-based compensation. We expect our expenses to increase in the near term as we initiate and complete additional clinical trials and associated programs related to RT002 injectable for the treatment of glabellar lines and indications in muscle movement and other disorders, such as cervical dystonia and plantar fasciitis.

#### Research and Development Expenses

We recognize research and development expenses as they are incurred. Since our inception, we have focused on our clinical development programs and the related research and development. We have been developing RT002 injectable and our topical product candidates since 2002 and we have typically shared our employees, consultants and infrastructure resources across both programs. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions, including stock-based compensation;

- expenses related to the initiation and completion of clinical trials for RT002 injectable and our topical product candidate, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, clinical trial sites, clinical research organizations (CROs) and other vendors, including all related fees for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- other consulting fees paid to third parties;
- expenses related to establishment and maintenance of our own manufacturing facilities;
- expenses related to the manufacture of drug substance and drug product supplies for ongoing and future preclinical and clinical trials;
- expenses to support our product development and establish manufacturing capabilities to support potential future commercialization of any products for which we may obtain regulatory approval;
- expenses related to license fees and milestone payments under in-licensing agreements;
- expenses related to compliance with drug development regulatory requirements in the United States, the European Union and other foreign jurisdictions; and
- depreciation and other allocated expenses.

Our research and development expenditures are subject to numerous uncertainties primarily related to the timing and cost needed to complete our respective projects. Further, the development timelines, probability of success and development expenses can differ materially from expectations and the completion of clinical trials may take several years or more depending on the type, complexity, novelty and intended use of a product candidate. Accordingly, the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development. We expect our research and development expenses to increase as we continue our clinical development of RT002 injectable for the treatment of glabellar lines, cervical dystonia, plantar fasciitis and any future new indications, or if the FDA requires us to conduct additional clinical trials for approval.

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect variations in our research and development expense. We expense both internal and external research and development expenses as they are incurred. We typically share employees, consultants and infrastructure resources between the RT002 injectable and our topical programs. We believe that the strict allocation of costs by product candidate would not be meaningful. As such, we generally do not track these costs by product candidate.

Our research and development expenses are summarized as follows:

	Three Months Ended March 31,		2018 vs. 2017
	2018	2017	%
Clinical and regulatory	11,885	10,312	15 %
Manufacturing and quality	5,996	5,230	15 %
Research	2,236	2,460	(9)%
Stock-based compensation	1,923	1,304	47 %
Other research and development expenses	199	102	95 %
Total research and development expenses	22,239	19,408	15 %

#### *Clinical and regulatory costs*

Clinical expenses include personnel and occupancy costs, and external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of RT002 injectable and our topical, including clinical trials of RT002 injectable for the improvement of glabellar lines, cervical dystonia and plantar fasciitis. For the three months ended March 31, 2018 and 2017, clinical and regulatory costs totaled \$11.9 million, or 53%, and \$10.3 million, or 53%, of research and development expenses for the respective periods.

Clinical and regulatory costs for the three months ended March 31, 2018 increased by 15%, compared to the same period in 2017, primarily due to the ongoing clinical trials for RT002 for the treatment of glabellar lines, cervical dystonia, and plantar

fasciitis. We expect our clinical and regulatory costs to increase in the near term as we initiate and complete clinical trials and other associated programs related to RT002 for the treatment of glabellar lines, cervical dystonia, plantar fasciitis and other indications, and the Company's anticipated BLA submission upon the completion and success of the clinical trials for the RT002 glabellar lines indication.

#### *Manufacturing and quality efforts*

Manufacturing and quality efforts include personnel and occupancy expenses, external contract manufacturing costs and pre-approval manufacturing of drug product used in research and our development of RT002 injectable and our topical product candidate. Manufacturing and quality efforts also include raw materials, lab supplies, and storage and shipment of our product candidates to support quality control and assurance activities. These costs do not include clinical costs associated with the development of RT002 injectable and our topical. For the three months ended March 31, 2018 and 2017, costs associated with our manufacturing and quality efforts for both RT002 injectable and topical development totaled \$6.0 million, or 27%, and \$5.2 million, or 27%, of research and development expenses for the respective periods.

Manufacturing and quality efforts for the three months ended March 31, 2018 increased by 15%, compared to the same period in 2017, primarily due to increased costs related to hiring additional personnel as well as an increase in outside services and consulting for compliance requirements and infrastructure buildout. We expect our manufacturing and quality efforts to continue to increase as the Company approaches commercialization.

#### *Research costs*

Research costs include expenses for personnel and occupancy, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of RT002 injectable and our topical product candidate. For the three months ended March 31, 2018 and 2017, costs associated with our preclinical development totaled, \$2.2 million, or 10%, and \$2.5 million, or 13%, of research and development expenses for the respective periods.

Research expenses for the three months ended March 31, 2018 decreased by 9%, compared to the same period in 2017, primarily due to decreased consulting costs on research projects. We expect our research costs to increase as the Company expands into other indications.

#### *Stock-based compensation*

Stock-based compensation for research and development for the three months ended March 31, 2018 increased by \$0.6 million, compared to the same period in 2017, primarily due to an increase in employee headcount and an increase in stock price.

#### *Other research and development expenses*

Other research and development expenses for the three months ended March 31, 2018 and 2017 includes license fees for BioSentinel, Inc.'s technology and expertise for research and development and manufacturing purposes. For the three months ended March 31, 2018 and 2017, other research and development expenses represented \$0.2 million, or 1%, and \$0.1 million, or 1%, of research and development expenses for the respective periods.

#### *General and Administrative Expenses*

We expect that our general and administrative expenses will increase with the continued development of, and if approved, the commercialization of RT002 injectable. The following table presents our general and administration expenses for the periods indicated and related changes from the prior period:

	Three Months Ended March 31,		2018 vs. 2017
	2018	2017	%
	(In thousands, except percentages)		
Finance and administration	6,768	5,511	23%
Commercial	4,613	392	1,077%
Stock-based compensation	2,235	1,851	21%
Total general and administrative expenses	13,616	7,754	76%

#### *Finance and administration*

Finance and administration expenses consist primarily of personnel and consulting costs, for employees in our finance, information technology, investor relations, legal, human resources and other administrative functions. Other significant expenses include professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and litigation. Finance and administration expenses for the three months ended March 31, 2018 increased by 23%, compared to the same period in 2017, primarily due to increased costs related to personnel and consulting costs to support the Company's infrastructure.

#### *Commercial*

Commercial expenses consist primarily of market research, public relations, promotion and advertising costs. Commercial expenses increased by 1,077% compared to the same period in 2017, due to increased costs related to personnel, consulting costs, and pre-commercial initiatives to support our anticipated future product launch for the RT002 glabellar lines indication.

#### *Stock-based compensation*

Stock-based compensation for selling, general and administrative expenses increased for the periods presented primarily due to an increase in employee headcount and an increase in stock price.

### ***Net Non-Operating Expenses***

#### *Interest Income*

Interest income consists primarily of interest income earned on our deposit, money market fund, and investment balances. We expect interest income to vary each reporting period depending on our average deposit, money market fund, and investment balances during the period and market interest rates. Interest income for the three months ended March 31, 2018 is consistent with the same period last year.

#### *Interest Expense*

Interest expense primarily consists of the interest charges associated with our financing obligations and capitalized interest. Interest expense, includes cash and non-cash components with the non-cash components consisting of effective interest recognized on the financing obligations and interest capitalized for assets constructed for use in operations.

#### *Change in Fair Value of Derivative Liability Associated with Medicis Settlement*

The Product Approval Payment associated with Medicis settlement is classified as a liability on our Condensed Consolidated Balance Sheet. This liability is remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the Condensed Consolidated Statement of Operations and Comprehensive Loss. We will continue to record adjustments to the fair value of the Medicis settlement derivative liability until the Product Approval Payment has been paid. The loss recorded during the three months ended March 31, 2018 reflects an increase to the valuation of the derivative liability based on assumptions related to the development of RT002 injectable for glabellar lines.

#### *Total Net Non-Operating Expenses*

The total net non-operating expenses is as follows:

	Three Months Ended March 31,		
	2018	2017	Change
	(In thousands, except percentages)		
Interest income	\$ 1,022	\$ 311	229%
Interest expense	(44)	(193)	(77)%
Change in fair value of derivative liability associated with Medicis settlement	(34)	(60)	(43)%
Other expense, net	(319)	(126)	153%
Total net non-operating expenses	<u>\$ 625</u>	<u>\$ (68)</u>	(1,019)%

Our total net non-operating expense for the three months ended March 31, 2018 decreased by 1,019%, compared to the same period in 2017, primarily due to a decrease in interest expense and the change in fair value of the derivative liability associated with the Medicis settlement. Interest expense for the three months ended March 31, 2018 decreased by 77%, compared to the same period in 2017, primarily due to the decreasing interest on the equipment leases with Essex Capital as the leases approach maturity. The decrease in the change in the fair value of derivative liability associated with the Medicis settlement is primarily due to recording additional expense in 2018 to increase to the valuation of the derivative liability based on time-based discounting and interest rates.

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

	March 31, 2018	December 31, 2017	Change
(In thousands)			
Cash, cash equivalents, and investments	\$ 268,806	\$ 282,896	\$ (14,090)
Financing obligations	983	1,872	(889)
Working Capital	250,422	264,309	(13,887)
Stockholders' Equity	236,641	268,845	(32,204)

### Sources and Uses of Cash

Our cash, cash equivalents and investments totaled \$268.8 million at March 31, 2018 compared to \$282.9 million at December 31, 2017, representing a decrease of \$14.1 million. We hold our cash, cash equivalents, and investments in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

The decrease in cash, cash equivalents and investments of \$14.1 million was primarily due to cash used in operations, purchases of property and equipment of \$1.1 million, and equipment lease payments on our financing obligations of \$0.9 million. These decreases were primarily offset by the receipt of \$25.0 million of cash proceeds from the upfront collaboration payment from Mylan (Note 3) and \$1.0 million from interest income received from investments.

Through March 31, 2018, we have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock, venture debt, and convertible debt. Due to our substantial research and development expenditures, we have generated significant operating losses since our inception. Our expenditures are primarily related to research and development activities. We expect to continue to incur net operating losses for at least the next several years as we advance RT002 injectable through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. As a result, we will need additional capital to fund our operations which we may obtain from additional financings, public offerings, or other sources. As of March 31, 2018, we had available cash, cash equivalents and investments of \$268.8 million.

We derived the following summary of our Condensed Consolidated Cash Flows for the periods indicated from our unaudited Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q (in thousands):

	Three Months Ended March 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	\$ (11,144)	\$ (21,192)
Investing activities	(200,318)	(28,574)
Financing activities	(2,222)	25,001

### Cash Flows from Operating Activities

Our cash used in operating activities is primarily driven by personnel, manufacturing costs, clinical development, and facility related expenditures. The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses, all which are highly variable. Our cash flows from operating activities will continue to be affected principally by our working capital requirements and the extent to which we increase spending on personnel and research and development activities as our business grows.

Net cash used in operating activities for the three months ended March 31, 2018 of \$11.1 million was primarily due to clinical spend of more than \$13 million to advance the Company's clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$11 million; and professional services and consulting of more than \$7 million, offset by cash receipts of \$25 million from Mylan upfront payment (Note 3) and \$1 million from investment interest income. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

Net cash used in operating activities of \$21.2 million in the three months ended March 31, 2017 was largely due to ongoing clinical trial activities for our RT002 injectable program and our topical product candidate, including more than \$3 million for payments to clinical trial vendors; investing in our personnel, including those that support the clinical programs, and talent retention, which represents more than \$8 million; and professional services and consulting of more than \$4 million. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

#### *Cash Flows from Investing Activities*

Net cash used in investing activities for the three months ended March 31, 2018, and 2017 was primarily due to purchases of property and equipment and fluctuations in the timing of purchases and maturities of investments.

#### *Cash Flows from Financing Activities*

Net cash provided by or used in financing activities are primarily driven by proceeds from the issuance of our common stock in connection with follow-on offerings (as described below), ATM offerings (as described below), stock option exercises and employee stock plan purchases. Decreases in our cash flows from financing activities are primarily due to principal payments on the aforementioned equipment lease with Essex Capital and payments to settle employee tax obligations resulting from net settlement of restricted stock awards.

#### *Follow-On Public Offerings*

In December 2017, the Company completed a follow-on public offering, or the 2017 follow-on offering, pursuant to which the Company issued 5,389,515 shares of common stock at \$31.00 per share, including the exercise of the underwriters' over-allotment option to purchase 550,806 additional shares of common stock, for net proceeds of \$156.9 million, after underwriting discounts, commissions and other offering expenses.

#### *At-The-Market Offering*

In March 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2016 ATM agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen as our sales agent. During the three months ended March 31, 2017, the Company sold 1,272,437 shares of its common stock under the 2016 ATM Agreement at a weighted average price of \$21.24 per share resulting in net proceeds of \$25.7 million, after underwriting discounts, commissions, and offering expenses.

In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of March 31, 2018.

#### ***Operating and Capital Expenditure Requirements***

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to continue to incur net losses for the foreseeable future. We expect to make additional capital outlays to increase operating expenditures over the next several years to support the completion of the clinical trials and other associated programs relating to RT002 injectable for the treatment of glabellar lines, cervical dystonia, plantar fasciitis and other indications, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We believe that our existing capital resources, the net proceeds from our

follow-on public and ATM offerings will be sufficient to fund our operations for at least the 12 months following the filing of this Form 10-Q. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for RT002 injectable, and our topical product candidate, and any future product candidates, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if we obtain marketing approval. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT002 injectable and preclinical trials of our topical product candidate or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT002 injectable, or any future product candidates including topical;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of RT002 injectable, topical, or any future product candidates;
- the cost of commercialization activities if RT002 injectable or any future product candidates including topical are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT002 injectable, topical, or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;

Please see Part II, Item 1A. "Risk Factors" for additional risks associated with our substantial capital requirements.

We have not generated product revenue from RT002 injectable or our topical product candidate, and we do not know when, or if, we will generate such revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize RT002 injectable or our topical product candidate. We expect our continuing operating losses to result in increases in cash used in operations over the next several years.

We have based our estimates of future capital requirements on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our ongoing clinical trials of RT002 injectable may encounter technical or other difficulties that could increase our development costs more than we currently expect or the FDA or EMA may require us to conduct additional clinical trials prior to approving RT002 injectable or future products we may develop. Our collaboration with Mylan to develop a biosimilar may or may not be successful. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials beyond 2018.

## **Critical Accounting Policies**

There have been no material changes in our critical accounting policies during the three months ended March 31, 2018, as compared to those disclosed in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 2, 2018, except as described in Footnote 2 of the Notes to the Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

## **Contractual Obligations**

Our minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC. Our future minimum contractual commitments have not changed materially from the amounts previously reported.

## **Recent Accounting Pronouncements**

Refer to "Recent Accounting Pronouncements" in Note 2 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

## **Off-Balance Sheet Arrangements**

As of March 31, 2018, we did not have any off-balance sheet arrangements or any relationships with any entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### **Overview**

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

### ***Interest Rate Sensitivity***

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and investments. We had cash, cash equivalents, and investments of \$268.8 million and \$282.9 million as of March 31, 2018 and December 31, 2017, respectively. As of March 31, 2018, our cash, cash equivalents, and investments were held in deposit, money market fund accounts, and U.S. government agency and treasury obligations. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. A hypothetical 10% movement in interest rates would not be expected to have a material impact on our Condensed Consolidated Financial Statements. We mitigate market risk for changes in interest rates by holding our investments in U.S. treasury and government agency obligations to maturity.

### ***Foreign Exchange***

Our operations are primarily conducted in the United States using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations are denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the three months ended March 31, 2018 and 2017, are included in other expense in the Condensed Consolidated Statements of Operations and Comprehensive Loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.



## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. 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 periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, 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 our disclosure controls and procedures as of March 31, 2018, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

There were no changes in our internal control over financial reporting during the three months ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

## ITEM 1A. RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below as well as all other information included in this Form 10-Q, including our Condensed Consolidated Financial Statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before you decide to purchase shares of our common stock. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.*

*We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2017.*

### **We are substantially dependent on the clinical and commercial success of our injectable product candidate RT002 injectable.\***

To date, we have invested substantial efforts and financial resources in the research and development of botulinum toxin-based product candidates. Our success as a company is substantially dependent on the clinical and commercial success of RT002 injectable.

We previously completed topical clinical trials for the treatment of lateral canthal lines (crow's feet) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results of our REALISE 1 Phase 3 clinical trial using topical to treat crow's feet.

We have invested substantial efforts and financial resources in the research and development of RT002 injectable. We are in Phase 3 clinical development for RT002 injectable in North America for the treatment of glabellar lines. During the fourth quarter of 2016, we initiated subject dosing in our SAKURA Phase 3 program. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program. In December 2017, we announced positive top-line results for DaxibotulinumtoxinA for Injection (RT002) in alleviating moderate-to-severe glabellar lines in two randomized, double-blind, placebo-controlled pivotal Phase 3 trials to evaluate the safety and efficacy of a single administration of RT002 for the treatment of moderate-to-severe glabellar lines in adults. The SAKURA 1 and SAKURA 2 trials enrolled more than 600 subjects at 30 sites in the United States and Canada. In addition to the two planned pivotal trials, the Phase 3 program includes a long-term open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety of RT002 injectable for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. The long-term safety trial enrolled more than 2,500 patients at 66 sites in the U.S. and Canada and is expected to be completed in the second half of 2018. Depending on the number of treatments and duration of follow-up, a subject may be on trial for a maximum of 86 weeks. We have designed SAKURA 3 to support a safety database adequate for both domestic and international marketing applications. In 2015, we reported positive results from BELMONT, a Phase 2 active comparator clinical trial against BOTOX® Cosmetic. Past results may not be indicative of results from future trials. Assuming successful completion of our SAKURA Phase 3 program in the second half of 2018, we plan to file marketing applications first in the United States in the first half of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries.

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia. The trial was designed to enroll 37 subjects following three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial's first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort of 13 subjects received from 300 to 450 units. In May 2017, we announced positive topline results from the Phase 2 trial. Past results may not be indicative of results from future trials. In November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we plan to initiate our Phase 3 program for cervical dystonia in the second quarter of 2018. The Phase 3 Program is expected to include a single pivotal trial and an open-label safety study. In November 2017, the FDA also granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

In 2016, we also initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study will evaluate the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the

United States in October 2017. The study's primary efficacy endpoint is the improvement in the American Orthopedic Foot and Ankle Score (AOFAS). In January 2018, we announced interim 8-week results from this study. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant. We plan to conduct another Phase 2, double-blind, placebo-controlled trial utilizing two doses of RT002 in the second half of 2018.

In April 2018, we announced two new clinical programs for RT002: adult upper limb spasticity and chronic migraine. We plan to initiate a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018. We also plan to initiate a Phase 2 study to treat chronic migraine in 2019.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of RT002 injectable. Our longer-term prospects will depend on the successful development, regulatory approval and commercialization of RT002 injectable, as well as our topical or any future product candidates. The preclinical, clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of, or need to conduct additional, clinical trials, including our clinical trials for RT002 injectable, topical, and any future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the number and design of such trials and the accurate and satisfactory performance of third-party contractors;
- our ability to demonstrate the effectiveness and differentiation of our products on a consistent basis as compared to existing or future therapies;
- our ability to demonstrate to the satisfaction of the FDA, the safety and efficacy of RT002 injectable, our topical product candidate, or any future product candidates through clinical trials;
- whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of RT002 injectable, our topical product candidate, or any future product candidates;
- our success in educating physicians and patients about the benefits, administration and use of RT002 injectable, our topical product candidate, or any future product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates or future approved products;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the ability to raise additional capital on acceptable terms and in the time frames necessary to achieve our goals;
- achieving and maintaining compliance with all regulatory requirements applicable to RT002 injectable, our topical product candidate, or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative treatments;
- the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to manufacture clinical trial supplies of RT002 injectable, our topical product candidate, or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to successfully commercialize RT002 injectable, our topical product candidate, or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;
- our ability to enforce our intellectual property rights in and to RT002 injectable, our topical product candidate, or any future product candidates;
- our ability to avoid third-party patent interference or intellectual property infringement claims;
- acceptance of RT002 injectable, our topical product candidate, or any future product candidates, if approved, as safe and effective by patients and the medical community; and
- the continued acceptable safety profile of RT002 injectable, our topical product candidate, or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of RT002 injectable, our topical product candidate, or any future product candidate to continue our business.

**We may be unable to obtain regulatory approval for RT002 injectable, topical product candidate, or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business prospects, and our results of operations.**

To gain approval to market a biologic product such as RT002 injectable or topical, we must provide the FDA and foreign regulatory authorities with data that adequately demonstrate the safety, efficacy and quality of the product for the intended indication applied for in the BLA or other respective marketing applications. The development of biologic products is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, including in Phase 3 development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway, safety or efficacy observations, including previously unreported adverse events; and the need to conduct further supportive or unanticipated studies, even after initiating Phase 3 trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful or that additional supportive studies will not be required, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Specifically, we completed topical clinical trials for the treatment of lateral canthal lines (crow's feet) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results from our REALISE 1 Phase 3 clinical trial for crow's feet. In addition, we announced in January 2018 that we plan to conduct a second Phase 2 study in plantar fasciitis.

Our business currently depends substantially on the successful development, regulatory approval and commercialization of our product candidates. Based on discussion with the FDA at a Pre-Phase 3 meeting in the second quarter of 2016 and the minutes received following the meeting, we submitted an IND in the United States and initiated subject dosing in Phase 3 clinical studies of RT002 injectable for the treatment of glabellar lines in 2016. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program and in October 2017, we completed enrollment of SAKURA 3. In December 2017, we announced positive top-line results from the two pivotal trials. We plan to move forward with studies required for submission of a BLA. Such studies may increase the time, expense and uncertainty of our RT002 injectable development program, including, for example, because results of such studies may indicate to us a further need to refine the RT002 injectable product candidate.

We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize RT002 injectable, or our topical product candidate. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market RT002 injectable in the United States until we receive approval of a BLA from the FDA. We are also not permitted to market RT002 injectable in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

The FDA or any foreign regulatory body can delay, limit or deny approval of our product candidates, including RT002 injectable, for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or an applicable foreign regulatory body that RT002 injectable, topical, or any future product candidates are safe and effective for the requested indication;
- our inability to demonstrate preclinical proof of concept of topical or other products in future, new indications;
- the FDA's or an applicable foreign regulatory agency's disagreement with the trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that clinical and other benefits of RT002 injectable, topical, or any future product candidates outweigh any safety or other perceived risks;
- the FDA's or an applicable foreign regulatory agency's requirement for additional preclinical or clinical studies;
- the FDA's or an applicable foreign regulatory agency's non-approval of the formulation, labeling or the specifications of RT002 injectable, topical, or any future product candidates;
- the FDA's or an applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or an applicable foreign regulatory agency to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for RT002 injectable, topical, or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA or the applicable foreign regulatory agency also may approve RT002 injectable, our topical product candidate, or any future product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates, and RT002 injectable in particular, would delay or prevent commercialization of RT002 injectable and would materially adversely impact our business, results of operations and prospects.

**We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.\***

Since our inception, most of our resources have been dedicated to the research and preclinical and clinical development of our botulinum toxin product candidates, RT002 injectable and topical. In particular, our clinical programs for RT002 injectable and topical will require substantial additional funds to complete. We had an accumulated deficit through March 31, 2018 of \$577.2 million and a working capital surplus of \$250.4 million as of March 31, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market, or ATM, offerings in 2015 and 2017. Our recorded net losses were \$35.0 million and \$27.2 million for the three months ended March 31, 2018, and 2017, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. As of March 31, 2018, we had capital resources consisting of cash, cash equivalents and investments of \$268.8 million. We raised aggregate net proceeds of \$126.2 million and \$156.9 million in our follow-on public offerings in November 2015 and December 2017, respectively. In addition, we raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, we terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of March 31, 2018. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT002 injectable, topical, and development of any other indications and product candidates that we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RT002 injectable and any future product candidates.

We believe that our existing cash, cash equivalents, and investments including the net proceeds from our IPO, follow-on public offerings, and ATM offerings will allow us to fund our operations for at least 12 months following the filing of this Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT002 injectable and preclinical trials of our topical product candidate or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT002 injectable, or any future product candidates including topical;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of RT002 injectable, topical, or any future product candidates;

- the cost of commercialization activities if RT002 injectable or any future product candidates including topical are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT002 injectable, topical, or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when needed, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, research, development, manufacturing, sales, marketing or other commercial activities for RT002 injectable, topical, or any future product candidate.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new equity securities may have a preference over our common stock. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures or specified financial ratios, any of which could restrict our ability to commercialize our product candidates or operate as a business.

**Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use necessary for commercial success.**

The commercial success of RT002 injectable, and any future product candidates including topical, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians for approved indications. The degree and rate of physician adoption of RT002 injectable and any future product candidates, if approved, will depend on a number of factors, including:

- the effectiveness and duration of effect of our product as compared to existing and future therapies;
- physician willingness to adopt a new therapy to treat glabellar lines, cervical dystonia, plantar fasciitis or other aesthetic or therapeutic indications;
- patient satisfaction with the results and administration of our product and overall treatment experience;
- patient demand for the treatment of glabellar lines, cervical dystonia, plantar fasciitis or other aesthetic or therapeutic indications;
- the willingness of third-party payors to reimburse physicians or patients for RT002 injectable and any future products we may commercialize for therapeutic indications; and
- the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If RT002 injectable or any future product candidates are approved for use but fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected.

**Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.**

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors in the pharmaceutical and medical device markets have the ability to effectively discover therapies, obtain patents, develop, test and obtain regulatory approvals for products, and have the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. Numerous companies are engaged in the developing, patenting, manufacturing and marketing healthcare products which we expect will compete with those that we are developing. Many of these competitors are large, experienced companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities.

Upon marketing approval, the first expected use of our products will be in aesthetic medicine. Competition in aesthetic products is significant and dynamic, and is characterized by rapid and substantial technological development and product innovations. Numerous competitors have obtained patents protecting what they consider to be their intellectual property.

In aesthetic medicine, we plan to seek regulatory approval of RT002 injectable for the treatment of glabellar lines. We anticipate that RT002 injectable, if approved, will face significant competition from existing injectable botulinum toxins as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for RT002 injectable from biosimilar products and products based upon botulinum toxin. To compete successfully, we will have to demonstrate that the treatment of glabellar lines with RT002 injectable is a worthwhile aesthetic treatment and has advantages over other therapies. Competition could result in reduced profit margins and limited sales, which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in a number of foreign countries than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in certain countries can make about the effectiveness of their products and the manner in which they can market them.

**We currently make our RT002 injectable clinical drug product exclusively in one internal manufacturing facility. We plan to utilize internal and external facilities, including through one or more third-party contractors, in the future to support commercial production if our product candidates are approved. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed.**

We currently manufacture our own clinical drug product to support RT002 injectable development in one internal manufacturing facility. In March 2017, we entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement, or the Services Agreement, with Ajinomoto Althea, Inc., or Althea, a contract development and manufacturing organization. Under the Services Agreement, Althea will provide us commercial fill/finish services and will serve as a second source of manufacturing for RT002 injectable. We plan to utilize our internal and external Althea facility to support commercial production of RT002 injectable, if approved. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of such manufacturing facilities is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved, jeopardize our ability to manufacture our products as promptly as our customers expect or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

Currently, we maintain insurance coverage totaling \$23.0 million against damage to our property, equipment and tenant improvements, \$2.0 million in general liability coverage, a \$9.0 million umbrella policy, and an additional \$45.0 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.



**Impairment in the carrying value of long-lived assets could negatively affect our operating results.\***

We constructed a fill/finish line dedicated to the manufacture of topical and to support our regulatory license applications. We discontinued further clinical development of topical for the treatment of crow's feet and for the treatment of primary axillary hyperhidrosis in June 2016, following the results from our REALISE 1 Phase 3 clinical trial. During the year ended December 31, 2016, we recorded a loss on impairment of \$9.1 million related to certain components of the topical fill/finish line and other long-lived assets. The Company assessed the topical fill/finish line and these other long-lived assets for impairment indicators and recorded a loss on impairment of \$2.9 million for the year ended December 31, 2017. There were no indicators of impairment for the three months ended March 31, 2018. As of March 31, 2018, the fill/finish line and these other long-lived assets had net book values of \$2.4 million and \$0.1 million, respectively. Under generally accepted accounting principles in the United States, long-lived assets, such as our fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, changes in operating plans, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in expected long-term sales or profitability. We will evaluate the recoverability and fair value of our long-lived assets, including those related to other components of the fill/finish line, each reporting period to determine the extent to which further non-cash charges to earnings are appropriate. Additional impairment in the value of our long-lived assets may materially and negatively impact our operating results.

**We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. Currently, we have only one product candidate in clinical trials and no commercial sales, which make it difficult to assess our future viability.\***

We are a clinical-stage biotechnology company. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to RT002 injectable or our topical product candidate. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We had an accumulated deficit through March 31, 2018 of \$577.2 million and a working capital surplus of \$250.4 million as of March 31, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market, or ATM, offerings in 2015 and 2017. Our recorded net losses were \$35.0 million and \$27.2 million for the three months ended March 31, 2018, and 2017, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. The net proceeds from the sale of the shares in our November 2015 and December 2017 follow-on public offerings and ATM offerings in 2015 and 2017, after deducting the underwriters' discount, commissions, and other offering expenses related to the respective offerings, were approximately \$126.2 million and \$156.9 million, \$10.0 million and \$38.2 million, respectively. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT002 injectable. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months following the filing of this Form 10-Q.

We expect to continue to incur losses for the foreseeable future, and we anticipate that these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize RT002 injectable. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and manufacture, market and commercialize our products successfully. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

**Even if RT002 injectable, topical, or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.**

Even if we obtain FDA or other regulatory approvals, RT002 injectable, topical, or any future product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful.

The degree and rate of market acceptance of RT002 injectable, topical, or any future product candidates for which we receive approval depends on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- the proper training and administration of our products by physicians and medical staff;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of payors and patients;
- the willingness of patients to pay for RT002 injectable, our topical product candidate, and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;
- the willingness of third-party payors to reimburse physicians or patients for RT002 injectable and any future products we may commercialize for therapeutic indications;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue and continue our business.

**Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.**

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Furthermore, final results may differ from interim results. For example, any positive results generated to date in clinical trials for RT002 injectable do not ensure that later clinical trials, including any RT002 injectable clinical trials for the treatment of glabellar lines, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety profile and efficacy despite having progressed through preclinical studies and initial clinical trials.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. We have suffered similar setbacks with the clinical development of our topical product candidate and we cannot be certain that we will not face other similar setbacks in the future for RT002 injectable or other clinical development programs. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past and may in the future experience delays in our ongoing clinical trials, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- recruit suitable subjects to participate in a trial;
- have subjects complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

Subject enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the data safety monitoring board, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure of inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, discovery of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

**We have no experience manufacturing our product candidates at full commercial scale. If our product candidates are approved, we will face certain risks associated with scaling up our manufacturing capabilities to support commercial production.**

We have developed an integrated manufacturing, research and development facility located at our corporate headquarters. We manufacture drug substance and finished dose forms of the drug product at this facility that we use for research and development purposes and clinical trials. We do not have experience in manufacturing our product candidates at commercial scale. If our product candidates are approved, we may need to expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities and potentially enter into additional relationships with third-party manufacturers. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our manufacturing facilities in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

**We currently contract with third-party manufacturers for certain components and services necessary to produce RT002 injectable and expect to continue to do so to support further clinical trials and commercial scale production if RT002 injectable is approved. This increases the risk that we will not have sufficient quantities of RT002 injectable or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.**

We currently rely on third-party manufacturers for certain components such as bulk peptide and services such as fill/finish services, necessary to produce RT002 injectable for our clinical trials, and we expect to continue to rely on these or other manufacturers to support our commercial requirements if RT002 injectable is approved. In particular, in March 2017, we entered into the Services Agreement with Althea, a contract development and manufacturing organization to provide us commercial fill/finish services and a second source of manufacturing for RT002 injectable. We plan to utilize our internal and external Althea facility to support commercial production of RT002 injectable, if approved. Some of our contracts with our manufacturers contain minimum order and pricing provisions and provide for early termination based on regulatory approval milestones.

Reliance on third-party manufacturers entails additional risks, including the reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of RT002 injectable, or any other product candidates or products that we may develop. Any failure or refusal to supply the components or services for RT002 injectable or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

**We depend on single-source suppliers for the raw materials necessary to produce our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.**

We and our manufacturers purchase the materials necessary to produce RT002 injectable for our clinical trials from single-source third-party suppliers. There are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and, if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through American Peptide Company, Inc., or American Peptide, which was acquired by Bachem. We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe that we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of RT002 injectable or any future product candidates, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of RT002 injectable or any future product candidates. If we or our manufacturers are unable to purchase these raw materials on acceptable terms and at sufficient quality levels or in adequate quantities if at all, the development of RT002 injectable and any future product candidates, or the commercial launch of any approved products, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

Furthermore, if there is a disruption to our or our third-party suppliers' relevant operations, we will have no other means of producing RT002 injectable or any future product candidates until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

**We currently have limited marketing and sales capabilities and no field sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize RT002 injectable or any other future product candidates, if approved, or generate product revenue.**

We currently have limited marketing and sales capabilities and no field sales organization. To commercialize RT002 injectable or any other future product candidates, if approved, in the United States, Europe and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If RT002 injectable receives regulatory approval, we expect to market RT002 injectable as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize RT002 injectable or any future product candidates. If we are not successful in commercializing RT002 injectable or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

**To establish our sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization and we may experience difficulties in managing this growth.\***

As of March 31, 2018, we had 136 employees. We will need to continue to expand our managerial, operational, and other resources to manage our operations and clinical trials, continue our development activities and commercialize RT002 injectable or any other product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials and manufacturing operations effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations.

**We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.**

Our corporate headquarters and other facilities, including our internal manufacturing facility, are located in the San Francisco Bay Area, which has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facility, enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. In particular, because we manufacture botulinum toxin in our facilities, we would be required to obtain further clearance and approval by state, federal or other applicable authorities to continue or resume manufacturing activities. The disaster recovery and business continuity plans we have in place currently are limited and may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, thereby increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

**We currently rely on third parties and consultants to conduct all our preclinical studies and clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize RT002 injectable or any future product candidates.**

We do not have the ability to independently conduct preclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs and clinical data management organizations, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs and good laboratory practices or GLPs, for conducting, monitoring, recording and reporting the results of clinical and preclinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We also rely on consultants to assist in the execution, including data collection and analysis, of our clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days' prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties or consultants conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCP, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. We may be unable to recover unused funds from these third-parties. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for, and will not be able to, or may be delayed in our efforts to, successfully commercialize the product candidate being tested in such trials.

**If RT002 injectable is approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, significant fines, penalties, and sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.**

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products, such as RT002 injectable, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Furthermore, the use of our products for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Any of these events could harm our business and results of operations and cause our stock price to decline.

**Even if RT002 injectable or any future product candidate is approved for commercialization, if there is not sufficient patient demand for such procedures, our financial results and future prospects will be harmed.**

Treatment of glabellar lines with RT002 injectable is an elective procedure, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo the treatment of glabellar lines with RT002 injectable or the treatment of other aesthetic indications we may pursue may be influenced by a number of factors, including:

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians recommend RT002 injectable to their patients;
- the extent to which RT002 injectable satisfies patient expectations;
- our ability to properly train physicians in the use of RT002 injectable or such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety and effectiveness of RT002 injectable versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and RT002 injectable in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by general economic and political conditions.

Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient demand for RT002 injectable or for any other future product candidate, once approved.

**We are subject to uncertainty relating to third-party reimbursement policies which, if not favorable for RT002 injectable or any future product candidates, could hinder or prevent their commercial success.**

Our ability to commercialize RT002 injectable or any future product candidates for therapeutic indications such as cervical dystonia or plantar fasciitis will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for RT002 injectable or any future product candidates, or we may be required to sell them at a discount.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of RT002 injectable in determining whether to approve reimbursement for RT002 injectable and at what level. Our business would be materially adversely affected if we do not receive approval for reimbursement of RT002 injectable from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which RT002 injectable will be reimbursed to a smaller patient set than we believe they are effective in treating.

In some foreign countries, particularly Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including RT002 injectable, to other available therapies. If reimbursement for our product is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

**If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any future products we develop.**

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

- decreased demand for RT002 injectable or any future product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of RT002 injectable or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing RT002 injectable we intend to expand our insurance coverage to include the sale of RT002 injectable as applicable; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

**We have been, and in the future may be, subject to securities class action and shareholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.**

We have been, and may in the future be, the target of securities class actions or shareholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. The Court granted final approval of the Settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.



**If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop RT002 injectable, topical, or any future product candidates, conduct our clinical trials and commercialize RT002 injectable, topical, or any future products we develop.**

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly L. Daniel Browne, our President and Chief Executive Officer, Abhay Joshi, Ph.D., our Chief Operating Officer, Caryn G McDowell, our Senior Vice President, General Counsel & Corporate Secretary, Lauren P. Silvermail, our Chief Financial Officer and Chief Business Officer, and Todd Zavodnick, our Chief Commercial Officer and President, Aesthetics and Therapeutics, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the completion of our planned clinical trials or the commercialization of RT002 injectable, topical, or any future products we develop.

Leadership transitions can be inherently difficult to manage. Resignations of executive officers may cause disruption in our business, strategic and employee relationships, which may significantly delay or prevent the achievement of our business objectives. Leadership changes may also increase the likelihood of turnover in other key officers and employees and may cause declines in the productivity of existing employees. The search for a replacement officer may take many months or more, further exacerbating these factors. Identifying and hiring an experienced and qualified executive officer are typically difficult. Periods of transition in senior management leadership are often difficult as the new executives gain detailed knowledge of our operations and may result in cultural differences and friction due to changes in strategy and style. During the transition periods, there may be uncertainty among investors, employees, creditors and others concerning our future direction and performance.

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense and the turnover rate can be high due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their previous research output.

**If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.**

Although a substantial amount of our effort will focus on the continued clinical testing and potential approval of RT002 injectable, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products for both aesthetic and therapeutic indications. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. While RT002 injectable is in the clinical development stage, topical and all of our other potential product candidates remain in the discovery or preclinical stage. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- intellectual property rights of third parties may potentially block our entry into certain geographies or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to problems that we encounter in developing and commercializing RT002 injectable.

**The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members of our board of directors.**

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Dodd-Frank Act, the Nasdaq listing rules and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company that is subject to these rules and regulations we may find it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

**Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.**

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including botulinum toxin type A, a key component of our product candidates, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We are licensed with the Centers for Disease Control and Prevention, or CDC and with the California Department of Health, Food and Drug Branch for use of botulinum toxin and to manufacture both the active pharmaceutical ingredient, or API, and the finished product in topical and injectable dose forms. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

**We may use third-party collaborators to help us develop, validate or commercialize any new products, and our ability to commercialize such products could be impaired or delayed if these collaborations are unsuccessful.\***

We may license or selectively pursue strategic collaborations for the development, validation and commercialization of RT002 injectable, topical, and any future product candidates. For instance, on February 28, 2018, we and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, entered into a collaboration agreement, or the Mylan Agreement, pursuant to which we and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize our product candidates. In any third-party collaboration, we would be dependent upon the success of the collaborators to perform their responsibilities with continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the demand for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect sales of RT002 injectable for the treatment of glabellar lines to be reimbursed by any government or third-party payor and, as a result, demand for the first indications of each of our product candidates will be tied to discretionary spending levels of our targeted patient population. Future global financial crises may cause extreme volatility and disruptions in capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for RT002 injectable, topical, or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current or future economic climate and financial market conditions could adversely impact our business.

**Adverse tax laws or regulations could be enacted or existing laws could be applied to us or our customers, which could increase the costs of our services and adversely impact our business.**

The application of federal, state, local and international tax laws to services provided electronically is evolving. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time (possibly with retroactive effect), and could be applied solely or disproportionately to services provided over the internet. These enactments could adversely affect our sales activity due to the inherent cost increase the taxes would represent and ultimately result in a negative impact on our operating results and cash flows.

In addition, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect), which could require us or our customers to pay additional tax amounts, as well as require us or our customers to pay fines or penalties and interest for past amounts. If we are unsuccessful in collecting such taxes from our customers, we could be held liable for such costs, thereby adversely impacting our operating results and cash flows.

Further, we have undertaken certain transactions to realize potential tax efficiencies in support of our expected global business expansion. These transactions are meant to align the global economic ownership of our intellectual property rights with our current and future business operations. We are uncertain as to whether the tax efficiencies sought by this alignment will materialize and may choose to unwind these transactions in the future.

On December 22, 2017, new legislation that significantly revises the Internal Revenue Code of 1986, as amended, was signed into law. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to

the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

### Risks Related to Our Intellectual Property

**If our efforts to protect our intellectual property related to RT002 injectable, or any future product candidates, including topical, are not adequate, we may not be able to compete effectively.**

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to RT002 injectable, topical, and our development programs. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thereby eroding our competitive position.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the United States or foreign countries. Competitors in the field of cosmetics, pharmaceuticals, and botulinum toxin have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents. Patents issued from applications filed after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility.

Under the *inter partes* review procedure, any third party may challenge the validity of any issued U.S. Patent in the United States Patent and Trademark Office, or USPTO, on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to RT002 injectable, topical, or any future product candidates is challenged, then it could threaten our ability to commercialize RT002 injectable, topical, or any future product candidates, and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market RT002 injectable, or any future product candidates under patent protection would be reduced. The results of our REALISE 1 Phase 3 clinical trial may be relevant to our patent strategy for our topical program.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios and financial resources than we have.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could significantly affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information.

**If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.**

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of cosmetics, pharmaceuticals and botulinum toxin have developed large portfolios of patents and patent applications in fields relating to our business. For example, there are patents held by third parties that relate to the treatment with botulinum toxin-based products for indications we are currently developing. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product based on our current or future indications, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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

Competitors may infringe upon our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation, *inter partes* review, post-grant review or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patents or patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, either alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

## Risks Related to Government Regulation

### **Our business and products are subject to extensive government regulation.**

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States, principally by the FDA, the U.S. Drug Enforcement Administration, or DEA, the CDC, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act, or FFDC, the Public Health Service Act, or PHSA, and Controlled Substances Act, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

After our products receive regulatory approval or clearance, we, and our direct and indirect suppliers, remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies (REMS) programs, completion of government mandated clinical trials, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls noted above.

### **The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of RT002 injectable or any future product candidates.**

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market RT002 injectable or any future product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for RT002 injectable anywhere in the world. After we submit a BLA for RT002 injectable, the FDA may refuse to file the application if it determines that the application is not sufficiently complete to permit substantive review. Even if filed by FDA, our BLA may receive a Complete Response Letter identifying deficiencies that must be addressed, rather than an approval. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical and clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval of a BLA or BLA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

- a product candidate may not be deemed safe, effective, or of required quality;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If RT002 injectable or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

**Even if we receive regulatory approval for RT002 injectable or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, may limit or delay regulatory approval and may subject us to penalties if we fail to comply with applicable regulatory requirements.**

Once regulatory approval has been granted, RT002 injectable or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our collaborators receive for RT002 injectable or any future product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the applicable regulatory agency approves RT002 injectable or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with RT002 injectable or any future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

**If we fail to obtain regulatory approvals in foreign jurisdictions for RT002 injectable, or any future product candidates including topical, we will be unable to market our products outside of the United States.**

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval procedures vary among countries and can involve additional clinical testing, or the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory



authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file, we may not receive the necessary approvals to commercialize our products in geographies outside of the United States.

**If approved, RT002 injectable or any other products may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so, we could be subject to sanctions that would materially harm our business.**

Some participants in our clinical trials have reported adverse events after being treated with RT002 injectable. If we are successful in commercializing RT002 injectable, or any other products including our topical product candidate, the FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

**We may in the future be subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.**

While we do not expect that RT002 injectable, if approved for the treatment of glabellar lines, will subject us to the various U.S. federal and state laws intended to prevent healthcare fraud and abuse, we may in the future become subject to such laws for treatment of other indications. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal healthcare programs and the levying of substantial civil and criminal penalties.

The federal False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

**Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of RT002 injectable, topical, or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.**

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of RT002 injectable, or any future product candidates including our topical product candidate. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could require, among other things:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

**Risks Related to the Ownership of Our Common Stock**

**The trading price of our common stock is volatile, and purchasers of our common stock could incur substantial losses.**

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock markets in general and the markets for pharmaceutical biopharmaceutical and biotechnology stocks in particular have experienced extreme volatility that may have been for reasons that are related or unrelated to the operating performance of the issuer. The market price for our common stock may be influenced by many factors, including:

- regulatory or legal developments in the United States and foreign countries;
- results from or delays in clinical trials of our product candidates, including our ongoing SAKURA Phase 3 clinical program in glabellar lines and our Phase 2 program in plantar fasciitis as well as our Phase 3 clinical program in cervical dystonia, all with RT002 injectable;
- announcements of regulatory approval or disapproval of RT002 injectable or any future product candidates;
- FDA or other U.S. or foreign regulatory actions or guidance affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- 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;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with customers and strategic partners; and
- other factors described in this "Risk Factors" section.

These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In addition, in the past, stockholders have initiated class actions against pharmaceutical companies, including us, following periods of volatility in their stock prices. Such litigation instituted against us could cause us to incur substantial costs and divert management's attention and resources.

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

As a smaller company, it may be difficult for us to attract or retain the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity and market price of our common stock. We will not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. We raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of March 31, 2018.

If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Any sales of securities by stockholders could have a material adverse effect on the trading price of our common stock.

**Provisions in our corporate charter documents and under Delaware law could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.**

Certain provisions in our amended and restated certificate of incorporation and amended and restated bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. Our board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- no cumulative voting in the election of directors;
- the ability of our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- the exclusive right of our board of directors to elect a director to fill a vacancy or newly created directorship;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders;
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- the ability of our board of directors, by a majority vote, to amend the bylaws; and
- the requirement for the affirmative vote of at least 66 2/3% or more of the outstanding common stock to amend many of the provisions described above.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

Our amended and restated certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders.

**A relatively small number of existing stockholders have substantial control over us, which could limit your ability to influence the outcome of key transactions, including a change of control.\***

As of March 31, 2018, our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 54.7% of our common stock. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

**Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.**

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**We are an “emerging growth company,” and if we decide to comply only with reduced disclosure requirements applicable to emerging growth companies, our common stock could be less attractive to investors.**

We are an “emerging growth company,” as defined in the JOBS Act and, for as long as we continue to be an “emerging growth company,” we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenues of over \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

### *Recent Sales of Unregistered Securities*

#### *Issuer Purchases of Equity Securities*

We have not and do not currently intend to retire or repurchase any of our shares other than providing our employees with the option to withhold shares to satisfy tax withholding amounts due from employees upon the vesting of restricted stock awards in connection with our 2014 Equity Incentive Plan.

<b>Period</b>	<b>Total Number of Shares Purchased (i)</b>	<b>Weighted-Average Price Paid per Share (ii)</b>	<b>Total Number of Share Purchased as Part of Publicly Announced Plan or Programs</b>	<b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan or Programs (in thousands)</b>
January 1 through January 31, 2018	18,844	\$ 34.37	—	—
February 1 through February 28, 2018	20,860	31.75	—	—
March 1 through March 31, 2018	11,255	31.65	—	—
<b>Total</b>	<b>50,959</b>	<b>\$ 32.69</b>	<b>—</b>	<b>—</b>

(i) Consists solely of shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock awards.

(ii) The weighted-average price paid per share is the weighted-average of the fair market prices at which we calculated the number of shares withheld to cover tax withholdings for the employees.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Exhibit Description	Incorporated by Reference to the Company's				Filed Herewith
		Form	File No.	Exhibit No.	Filed On	
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-36297	3.1	February 11, 2014	
3.2	<a href="#">Amended and Restated Bylaws</a>	S-1	333-193154	3.4	December 31, 2013	
4.2	<a href="#">Form of Common Stock Certificate</a>	S-1/A	333-193154	4.4	February 3, 2014	
10.1+	<a href="#">Collaboration and License Agreement by and between the Company and Mylan Ireland Ltd, dated as of February 28, 2018</a>					X
10.2*	<a href="#">Revance Therapeutics, Inc. 2018 Management Bonus Plan</a>	10-K	001-36297	10.26	March 2, 2018	
10.3	<a href="#">Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated as of March 13, 2018, by and between the Company and Cantor Fitzgerald &amp; Co.</a>	8-K	001-36297	99.1	March 13, 2018	
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</a>					X
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</a>					X
32.1†	<a href="#">Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
32.2†	<a href="#">Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
101.INS**	XBRL Instance Document					X
101.SCH**	XBRL Taxonomy Extension Schema Document					X
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB**	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document					X

\* Indicates a management contract or compensatory plan or arrangement.

+ Confidential treatment has been requested for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

- † The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, and shall not be deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act. Such certifications shall not be deemed incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.
- \*\* Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**REVANCE THERAPEUTICS, INC.**

Date: May 9, 2018

By: /s/ L. Daniel Browne

**L. Daniel Browne**  
**President and Chief Executive Officer**  
**(Duly Authorized Principal Executive Officer)**

Date: May 9, 2018

By: /s/ Lauren P. Silvernail

**Lauren P. Silvernail**  
**Chief Financial Officer and Chief Business Officer**  
**(Duly Authorized Principal Financial Officer)**



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

## COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this “**Agreement**”) is made as of February 28, 2018 (the “**Signing Date**”), by and between Mylan Ireland Ltd., an Irish company having principal offices at South Bank House, Barrow Street, 6<sup>th</sup> Floor, Dublin, Ireland (together with its successors and assigns, “**Mylan**”), and Revance Therapeutics, Inc., a Delaware corporation, having principal offices at 7555 Gateway Blvd., Newark, CA 94560 (together with its successors and assigns, “**Revance**”). Mylan and Revance may be referred to herein by name or individually, as a “**Party**” and collectively, as the “**Parties**.”

### BACKGROUND

- A. Revance is a pharmaceutical company developing certain products containing botulinum toxin.
- B. Mylan is a global pharmaceutical company primarily in the business of developing, manufacturing and marketing generic pharmaceutical products and biosimilars.
- C. The Parties desire to collaborate to develop a biosimilar version of the branded biologic product marketed as Botox® in certain countries as of the Effective Date.
- D. Mylan wishes to obtain certain exclusive rights and licenses to intellectual property from Revance for the development, manufacture and commercialization of Product in the Mylan Territory (each, as defined below); and
- E. Revance is willing to grant such exclusive rights and licenses to intellectual property to Mylan for Mylan to develop, manufacture and commercialize Product in the Mylan Territory, all on the terms and conditions set forth below.

**NOW, THEREFORE**, in consideration of the covenants, conditions and undertakings hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

### AGREEMENT

#### ARTICLE 1 DEFINITIONS

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

1.1 **“Accounting Standards”** means, with respect to a Person, U.S. Generally Accepted Accounting Principles (GAAP), consistently applied by such Person.

1.2 **“Affiliate”** means, with respect to a Party, any corporation, limited liability company or other business entity controlling, controlled by or under common control with such Party, for so long as such relationship exists. For the purposes of this definition, control means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such corporation, limited liability company or other business entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) ownership of more than fifty percent (50%) of the voting stock in such corporation, limited liability company or other business entity (or such lesser percent as may be the maximum that may be owned pursuant to Applicable Law of the country of incorporation or domicile), as applicable. For clarity, once a Person ceases to be an Affiliate of a Party, then, without any further action, such Person shall cease to have any rights, including license and sublicense rights, under this Agreement by reason of being an Affiliate of such Party.

1.3 **“Ancillary Agreement”** means the Supply Agreement, the Quality Agreement or the PV Agreement.

1.4 **“Annual Net Sales”** means, with respect to a calendar year, total Net Sales by Mylan or its Affiliates or their respective Sublicensees in the Mylan Territory in such calendar year.

1.5 **“Applicable Law”** means all laws, ordinances, rules, rulings, directives and regulations of any Regulatory Authority that apply to the development, manufacture, processing or commercialization of the Product or the other activities contemplated under this Agreement, including (a) all applicable federal, state and local laws, rules and regulations; (b) the BPCI Act, the Public Health Service Act and the U.S. Federal Food, Drug and Cosmetic Act; (c) Article 6 of Regulation (EC) 726/2004 and Article 10(4) of Directive 2001/83/EC; (d) 42 C.F.R., Part 73 and other applicable laws and regulations relating to toxins, (e) regulations, guidelines and procedural advice of the EMA, the FDA and other Regulatory Authorities, including guidelines of the Committee for Medicinal for Human Use (CHMP) and ICH; and (f) any applicable equivalents of any of the foregoing in the Mylan Territory.

1.6 **“Bankruptcy Event”** means, with respect to a Party, (a) the making by it of a general assignment for the benefit of creditors, (b) the commencement by it of any voluntary petition in bankruptcy or suffering by it of the filing of an involuntary petition of its creditors (that is not discharged within sixty (60) days of the filing thereof), (c) the suffering by it of the appointment of a receiver to take possession of all, or substantially all, of its assets, (d) the suffering by it of the attachment or other judicial seizure of all, or substantially all, of its assets, (e) the admission by it in writing of its inability to pay its debts as they come due, or (f) the making by it of an offer of settlement, extension or composition to its creditors generally.

1.7 **“Biological Active Substance”** means any botulinum neurotoxin [\*], including as further described on Exhibit 1.7.

1.8 **“Biosimilar”** means a product that: (a) is highly similar to the Reference Product notwithstanding minor differences in clinically inactive components; and (b) has no clinically meaningful differences from the Reference Product in terms of safety, purity and potency; and (c) would be eligible for review and approval by the FDA under the BPCI Act or equivalent EU guidelines or corresponding

Applicable Laws elsewhere in the Mylan Territory, regardless of whether Marketing Authorization is sought under the BPCI Act or such EU equivalent guidelines or such corresponding Applicable Law.

1.9 “**BLA**” means a Biologics License Application filed pursuant to the requirements of the FDA under 21 C.F.R., Section 601.2, to obtain Marketing Authorization for the Product in the United States.

1.10 “**BPCI Act**” means the Biologics Price Competition and Innovation Act of 2009 within the Patient Protection and Affordable Care Act, as set forth in Section 351(k) of the PHS Act (42 U.S.C. 262), which was signed into law in the United States in March 2010, and as may be subsequently amended.

1.11 “**Business Day**” means any day other than a Saturday, a Sunday or any day on which commercial banks located in New York City, New York, U.S.A. are authorized or required to remain closed.

1.12 “**Cell Line**” means the cell line described on Exhibit 1.12 hereto.

1.13 “**Cell Line Agreement**” means that certain [\*] Agreement by and between Revance and [\*], pursuant to which Revance has certain rights to the Cell Line.

1.14 “**cGMP**” means the current good manufacturing practice regulations as described in the U.S. Code of Federal Regulations, Parts 210, 211, 601, and 606, any applicable corresponding regulations promulgated in the European Union (or in any country currently in the European Union) or by the Brazilian Health Regulatory Agency (ANVISA), or ICH Guidelines.

1.15 “**Clinical Trial**” means any clinical study involving the administration of the Product to a human subject for the purpose of evaluating the safety, efficacy, performance or other characteristic of the Product.

1.16 “**Collaboration Data**” means any Product-Related Data generated by or on behalf of either Party or its Affiliates pursuant to this Agreement.

1.17 “**CMC**” means chemistry, manufacturing and controls, and may also be referred to as Pharmaceutical Quality/CMC.

1.18 “**Commercially Reasonable Efforts**” means, with respect to a Party’s activities hereunder, that level of effort and resources normally dedicated by such Party to the development, manufacture or commercialization, as the case may be, of such Party’s other pharmaceutical or medicinal products of a similar commercial potential at a similar stage in its lifecycle, consistent with Applicable Law, in each case taking into account issues of safety and efficacy, cost, product profile (including patent protection status), the then-current competitive environment for such product and the likely timing of such product’s entry into the market, the regulatory environment and status of such product, and other relevant scientific, legal, technical and commercial factors, all based on conditions prevailing at the time such efforts are due.

1.19 “**Control**” or “**Controlled**” means, with respect to Patent Rights or Know-How, possession by a Party of the power and authority, whether arising by ownership, license, or other authorization, to

grant and authorize the licenses or sublicenses, as applicable, under such intellectual property rights or Know-How of the scope granted to the other Party in this Agreement without violating the terms of any agreement or other arrangement with any Third Party, or, with respect to any Patent Right or Know-How obtained by a Party after the Signing Date from a Third Party, without being obligated to pay any royalties or other consideration therefor unless the Party receiving rights to such Patent Right or Know-How under this Agreement agrees in advance of any grant of rights thereto to pay such royalties or other consideration.

1.20 “**Cover**” means (a) with respect to Licensed Know-How, such Licensed Know-How was used in the Exploitation of the Product, and (b) with respect to a Licensed Intellectual Property Right, a Valid Claim of a Patent Right included therein would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of the Product; *provided, however*, that in determining whether a Valid Claim that is a claim of a pending application would be Infringed, it shall be treated as if issued as then-currently being prosecuted. Cognates of the word “**Cover**” shall have correlative meanings.

1.21 “**Development**” means all research, pre-clinical and clinical development activities that are necessary or useful to file for, obtain or maintain Marketing Authorization for the Product, whether such activities are conducted prior to the filing of an MAA for the Product in any country in the Mylan Territory or thereafter. Development activities may include: (a) design of a biological process or chemical process to manufacture the Product; (b) optimization of the Cell Line for production of the Product; (c) stability studies and quality analysis and quality control activities for the Product, including the creation and implementation of a process validation strategy; (d) formulation of the Product (including for bulk process intermediate and drug product) and associated stability studies; (e) creation and implementation of the Product manufacturing process and strategy; (f) pre-clinical and clinical manufacture of the Product, including the manufacture of registration, scale up and stability batches; (g) non-clinical characterization of the Product and the applicable Reference Product to determine similarity or interchangeability; (h) preclinical studies and Clinical Trials, bioequivalence studies, creation of analytical assays, data management, review and engagement of contract research organizations, preclinical and clinical document preparation, and other administrative activities associated with a clinical testing program; (i) regulatory affairs for the Product prior to obtaining Marketing Authorization to market the Product, including the preparation and filing of applications for Marketing Authorization, and the development and selection of the Product label; and (j) statistical analysis in connection with the foregoing activities.

1.22 “**Development Costs**” means the costs actually incurred by or on behalf of a Party, including all FTE costs measured at the FTE Rate and out-of-pocket costs paid by a Party to Third Parties (collectively), after the Effective Date in connection with the Development of the Product (a) in accordance with (i) the Initial Development Plan or (ii) the Development Plan and Development Budget, as applicable, or (b) (i) subject to and in accordance with Section 5.3(f), outside the Development Plan or (ii) subject to and in accordance with Section 5.2(b), outside the Initial Development Plan, and in each case (a) and (b), as determined from the books and records of the applicable Party or its Affiliates maintained in accordance with the Accounting Standards. Notwithstanding the foregoing, Development Cost shall exclude [\*], which shall be [\*], all [\*], which shall be [\*] and all [\*]. Development Costs shall include [\*] associated with [\*] to the extent [\*], as well as [\*].

1.23 “**Distributor**” means a Third Party, to whom a Party, its Affiliate or Sublicensee grants the right to market, promote, advertise, detail or co-promote, and sell or distribute the Product in one or more jurisdictions, which Third Party does not have the right to manufacture Product and purchases

Product from such Party, its Affiliates or its Sublicensees (or their designee, as applicable) for resale without making any modifications to such Product other than label changes to the packaging to include such Third Party's trademarks or trade dress and repackaging required under Applicable Law. For clarity, "**Distributor**" does not include wholesalers or logistic service providers.

1.24 "**EMA**" or "**European Medicines Agency**" means the European Union agency for the evaluation of medicinal products, or any successor entity thereto.

1.25 "**EU Major Market Country**" means each of the United Kingdom, Germany, France, Spain and Italy.

1.26 "**Europe**" means Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

1.27 "**European Product Revenues**" means Net Sales of Product sold by Mylan or its Affiliates or their respective Sublicensees in Europe.

1.28 "**Exploit**" means to research, develop, make, have made, use, offer for sale, sell, import, export, otherwise commercialize or otherwise exploit, or transfer possession of or title in, a product. Cognates of the word "**Exploit**" shall have correlative meanings.

1.29 "**FDA**" means the United States Food and Drug Administration, or any successor agency thereto performing similar functions.

1.30 "**FDA Scientific Advice Meeting**" means a Biosimilar Initial Advisory Meeting with the FDA for the Product, as described in the Guidance for Industry issued by FDA in November 2015 and entitled, "Formal Meetings between the FDA and Biosimilar Biological Product Sponsors or Applicants," as may be amended.

1.31 "**Financial Exhibit**" means Exhibit 1.31 attached hereto.

1.32 "**First Commercial Sale**" shall mean the first day on which a Party, its Affiliate, Distributor or, as applicable, Sublicensee or licensee sells the Product to a Third Party customer after the required Marketing Authorization to sell the Product has been granted by the applicable Regulatory Authority(ies).

1.33 "**FTE**" means the equivalent of the work of one (1) employee full-time for one (1) year (consisting of a total of [\*] hours per year, or such other number as may be agreed by the JSC) on or directly related to the Development of the Product in accordance with the Development Plan. Any individual who devotes less than [\*] hours per year (or such other number as may be agreed by the JSC) shall be treated as an FTE on a pro-rata basis upon the actual number of hours worked divided by [\*] (or such other number as may be agreed by the JSC). Unless modified by the JSC, the [\*] hour figure shall be used without regard to the Parties' own internal definition of the number of hours that comprises an FTE.

1.34 **“FTE Rate”** means [\*] per FTE. The FTE Rate shall include costs of salaries, benefits, supplies, other employee costs, facility costs, depreciation and supporting general and administration allocations.

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

1.36 **“ICH”** means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as implemented from time to time by the applicable Regulatory Authority.

1.37 **“Infringe” or “Infringement” or “infringe” or “infringement”** means any infringement as determined by Applicable Law, including, without limitation, direct infringement, contributory infringement or any inducement to infringe.

1.38 **“Initial Clinical Trial”** means a human clinical trial of the Product (as required by the applicable Regulatory Authority) conducted to generate pharmacokinetic and (if relevant pharmacodynamic measures exist) pharmacodynamic data that the Product is comparable to the applicable Reference Product, for purposes of supporting an application for Marketing Authorization under the BPCI Act, or equivalent approval process in other countries within the Territory.

1.39 **“Innovator”** means Allergan Inc., and its Affiliates, or any successor in interest thereto with respect to Botox® (including such product sold under other trademarks), together in each case with Persons acting under authority thereof or in collaboration therewith, whether by contract, pursuant to a joint venture or otherwise.

1.40 **“Know-How”** means any and all information comprising (a) ideas, discoveries, inventions (including Patented inventions and supporting data or descriptions), improvements or trade secrets; (b) Product-Related Data; (c) any business plans, designs, technical data, customer data, financial information, pricing and cost information, bills of material, or other similar information; (d) databases, practices, methods, techniques, specifications, formulations, formulae, and knowledge; and (e) manufacturing techniques, processes, and information.

1.41 **“Legal Clearance Activities”** means alternative development strategies, licensing strategies, litigation strategies (including declaratory judgments), invalidity strategies, administrative patent challenge procedures, Post-Grant Review Proceedings, patent clearance under the BPCI Act patent exchange and litigation process (or similar processes under Applicable Law in the Mylan Territory), and other approaches that optimize the success of the Product and launch timing.

1.42 **“Licensed Intellectual Property Rights”** means any and all Patent Rights (including the Licensed Patents) Controlled by Revance or any of its Affiliates as of the Signing Date or during the Term that are reasonably necessary for, or otherwise Cover, in whole or in part, the Product, the Biological Active Substance, or other components of the Product, or the development, manufacture, processing, use or commercialization thereof.

1.43 **“Licensed Know-How”** means any and all Know-How Controlled by Revance or any of its Affiliates as of the Signing Date or during the Term that is reasonably necessary for, or was (or is) used by Revance or any Affiliate in, the development, manufacture, processing, use or commercialization of the Product, the Biological Active Substance or any other component of the Product, including Revance and its Affiliates’ interest in and to the Collaboration Data.

1.44 **“Licensed Materials”** means any and all research materials, reagents, compositions of matter, cell lines and other biological material and chemical compounds Controlled by Revance or any of its Affiliates as of the Signing Date or during the Term that are reasonably necessary for the development, manufacture, processing, use or commercialization of the Product, including the research materials, reagents, compositions of matter, cell lines and other biological material and chemical compounds listed on Exhibit 1.44 hereto.

1.45 **“Licensed Patent(s)”** means the patents and patent applications listed on Exhibit 1.45 hereto, and all associated Patent Rights.

1.46 **“Licensed Technology Rights”** means, individually and collectively, the Licensed Intellectual Property Rights, Licensed Materials and Licensed Know-How.

1.47 **“Manufacturing Costs”** means the actual costs of manufacturing a Product. Manufacturing Costs will be calculated consistently with other products manufactured by Revance and in accordance with Accounting Standards. For clarity, in the event that Revance uses a Third Party contract manufacturer to perform any manufacturing activities under this Agreement or the Supply Agreement, Manufacturing Costs for such activities means the amount paid by Revance or its Affiliates to such a Third Party in connection with the manufacture and supply of such Product (including without limitation expenses related to storage, shipping, handling, insurance, customs duties or excise taxes), [\*]. Manufacturing Costs will exclude general administrative or corporate overhead and any other costs not directly attributable or allocable to the manufacture of the Product.

1.48 **“Marketing Authorization Application”** or **“MAA”** means a Regulatory Filing that is an application for Marketing Authorization for the Product, or any amendments or supplements to such Regulatory Filing, submitted or to be submitted to the FDA, EMA or other Regulatory Authorities in the Mylan Territory.

1.49 **“Marketing Authorization”** means, with respect to a country, all approvals, licenses, registrations, and regulatory authorizations required to make, store, import, transport, market and sell the Product in such country as granted by the relevant Regulatory Authority, including and any such pricing, labeling or reimbursement approvals, as applicable.

1.50 **“Mylan Know-How”** means any and all Know-How Controlled by Mylan or any of its Affiliates that (a) falls within the definition of Mylan Inventions and (b) is reasonably necessary for, or is or was used by Mylan or any Affiliate in, the development, manufacture, processing or commercialization of the Product.

1.51 **“Mylan Patents”** means any Patent Rights Controlled by Mylan or its Affiliates during the Term to the extent they claim Mylan Know-How.

1.52 “**Mylan Technology Rights**” means, individually and collectively, Mylan Patents and Mylan Know-How.

1.53 “**Mylan Territory**” means worldwide, excluding the Revance Territory.

1.54 “**Net Sales**” means the actual gross amounts invoiced by a Party, its Affiliates or their respective Sublicensees (each, a “**Selling Party**”) for sales of the Product to a Third Party customer, less the following deductions (and any other deductions taken in accordance with Accounting Standards) to the extent included in such gross amounts invoiced or otherwise incurred by the Selling Party with respect to the sale of such Product: (a) any quantity, prompt payment, trade, cash and other discounts actually given, including re-procurement and back-order charges; (b) credits, refunds, charge-backs, reimbursements, fee and rebates granted to customers, including distributors, group purchasing organizations, managed health care organizations, buying groups, health insurance carriers/agencies, or to national, state or local governments, their respective agencies, purchasers or reimbursers (including rebates and payments required to be paid to governmental entities in connection with sales of the Product pursuant to the Omnibus Budget Reconciliation Act of 1990 and similar national, state or local legislation or programs), adjustments arising from consumer or physician discount or loyalty programs, co-pay assistance programs or other similar programs; (c) retroactive price reductions, sales deductions, credits or allowances, including for recalls or damaged, rejected or expired goods or any other allowances actually given that effectively reduce the gross selling price; (d) customary fees paid to distributors, including group purchasing organizations; (e) sales credits accrued in accordance with Accounting Standards, including price protection, shelf stock or floor adjustments, adjustments for uncollectible accounts (capped at [\*] of Net Sales for the applicable period), billing errors and other price adjustments; (f) returns of Product for any reason; (g) freight, postage, shipping, handling and insurance charges with respect to such Product; and (h) sales taxes, excise taxes, use taxes, import/export duties or other governmental charges actually due or incurred with respect to such Product, including value-added taxes, in each case to the extent not reimbursed. Each of the foregoing deductions shall be determined as incurred in the ordinary course of business in accordance with Accounting Standards.

For clarity, sales of Product between a Party and its Affiliates or their respective Sublicensees for resale shall be excluded from Net Sales, but the subsequent resale of Product to a Third Party shall be included in Net Sales. However, sales of Product by a Party or its Affiliates or their respective Sublicensees to Distributors, and not the subsequent sale of such Product by the Distributor to a Third Party, shall be included in Net Sales. Sales of the Product used for promotional or advertising purposes (including samples) or used for research or development purposes (including for Clinical Trials) or for compassionate use or other donations shall not be included in Net Sales.

If any Product is sold in combination with one or more other products (e.g., a delivery device) or active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a “**Combination**”), then the gross amount received for that Product shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction  $A/(A+B)$ , where “A” is the gross amount invoiced for the Product sold separately and “B” is the gross amount invoiced for the other active ingredient(s) sold separately. If the other product or active ingredient is not sold separately, then the gross amount received for that Product shall be calculated by multiplying the gross amount received for the Combination by the fraction  $A/C$ , where “A” is the gross invoice amount for the Product, if sold separately, and “C” is the gross amount received for the Combination.



1.55 **“Patent Rights”** means any provisional and non-provisional patents and patent applications, together with all additions, divisions, continuations, continuations-in-part, substitutions, and reissues claiming priority thereto, as well as any re-examinations, extensions, registrations, patent term extensions, supplemental protection certificates, renewals and the like with respect to any of the foregoing and all foreign counterparts thereof.

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

1.57 **“Phase III Clinical Trial”** means a study in humans of the efficacy and safety of the Product, which is prospectively designed to (a) demonstrate statistically whether the Product is effective and safe for use in a particular indication in a manner sufficient to file for Marketing Authorization, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(c) or (b) confirm that the Product is (i) highly similar to the Reference Product notwithstanding minor differences in clinically inactive components, and (ii) has no clinically meaningful differences from such Reference Product in terms of safety, purity and potency.

1.58 **“PHS Act”** means the Public Health Service Act (42 U.S.C., Chapter 6A).

1.59 **“Post-Grant Review Proceeding”** means a proceeding conducted with respect to a patent before a patent office or other administrative agency that is not a court of law following the grant or issuance of such patent and pursuant to which the validity, enforceability or scope of such patent is challenged by a Person other than the patent holder, including a post-grant opposition proceeding, *ex parte* reexamination, *inter partes* review and other post-grant review proceedings. An appeal, including to a court of law, from such a Post-Grant Review Proceeding, shall be understood to be encompassed by the term Post-Grant Review Proceeding.

1.60 **“Product(s)”** means any and all products in finished form (and in any formulation, form or dosage strength) incorporating the Biological Active Substance as the sole active ingredient, which are Biosimilar(s). A product that would be eligible for review and approval under the BPCI Act or equivalent EU guidelines as a Biosimilar shall be included in the definition of Product throughout the Territory, regardless of whether such product is approved or eligible for approval as a biosimilar under corresponding Applicable Laws in each country in which it is marketed or sold. Product shall include, where applicable, any formulation, delivery device, dispensing device or packaging required for effective use of the Product. For clarity, Products shall exclude biological products incorporating the Biological Active Substance that are not Biosimilars, including Revance’s product candidates RT001 and RT002 (such product candidates, the **“Existing Revance Products”**).

1.61 **“Product-Related Data”** means any and all information, data and materials of any type directly related to the Product, whether or not proprietary, including the following: research, development, manufacturing and commercialization data: medicinal chemistry data, pre-clinical data, pharmacology data, chemistry data (including analytical, product characterization, toxicology data), clinical data (including original patient report forms, investigator reports (both preliminary and final reports), clinical protocols, statistical analyses, expert opinions and reports, safety and other electronic databases), manufacturing data (including analytical and quality control data and stability data, and other chemistry, manufacturing, and control (CMC) data), records and materials (including the Cell Line and other cell

lines and vectors), correspondence to and from Regulatory Authorities, minutes from teleconferences with Regulatory Authorities, Regulatory Filings and Marketing Authorizations, adverse drug reaction/experience files and complaint files, reports from contract research organizations, market research, annual reports to Regulatory Authorities, investigators' brochures, commercialization plans and customer lists, in each case, together with all supporting data and raw source data; *provided, however*, Product-Related Data shall exclude any and all patient-specific and other similar data to the extent required by Applicable Law.

1.62 **“Reference Product”** means (a) the injectable product containing botulinum neurotoxin serotype A as its sole active ingredient as marketed and manufactured by or on behalf of or under the authority of the Innovator as BOTOX® as of the Effective Date, together with any and all (b) modifications to the foregoing product described in (a) that do not change the function or therapeutic activity (including safety, purity and potency) or that do not require the conduct of a new full clinical program (Phase I through Phase III), (c) additional strengths and concentrations of any such product described in (a) or (b) that do not require the conduct of a new full clinical program (Phase I through Phase III), (d) devices for delivery of any such product described in (a), (b) or (c) by injection, and (e) such products described in (a), (b), (c) or (d) marketed under a different trademark or trade name, in each case ((b)-(e)): marketed and manufactured by or on behalf of or under the authority of the Innovator at any time during the Term. For clarity, the definition of Reference Product expressly excludes [\*].

1.63 **“Region”** means each of the following countries or regions: [\*]. Notwithstanding the foregoing, if, pursuant to Section 14.4(a), Mylan (x) terminates this Agreement with respect to [\*], then [\*] shall, collectively, be a Region subject to such termination, or (y) terminates this Agreement with respect to the [\*], then [\*] shall be a Region subject to such termination.

1.64 **“Regulatory Authority”** means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the development, manufacture or commercialization (including with respect to the granting of Marketing Authorizations) of the Product in any jurisdiction, including the FDA and EMA.

1.65 **“Regulatory Filing”** means any and all filings or applications submitted to a Regulatory Authority with respect to the Product (together with supporting documentation), including MAAs.

1.66 **“Revance Territory”** means Japan, any Reverted Country and any Terminated Country.

1.67 **“Reverted Country Product Revenues”** means, as to a given Reverted Country for a particular calendar quarter: (a) Net Sales of Product sold by Revance or its Affiliates (but not their respective Sublicensees) during such quarter, less (i) the Manufacturing Costs of such Product during such quarter, and (ii) actual marketing and distribution expenses incurred by Revance or its Affiliates with respect to the Product in such Reverted Country, [\*], plus (b) Sublicense Revenue received by Revance or its Affiliates during such quarter, in consideration for Sublicenses granted, less Sublicense Expenses incurred by Revance or its Affiliates with respect to Sublicenses granted during such quarter.

1.68 **“ROW Product Revenues”** means Net Sales of Product sold by Mylan or its Affiliates or their respective Sublicensees in the Mylan Territory outside of the U.S. and Europe.

1.69 “**ROW Target Country**” means each of [\*].

1.70 “**Sublicense Expenses**” all amounts paid or otherwise incurred by a Party or its Affiliate in connection with the negotiation and execution of or pursuant to obligations owed under an agreement granting a Third Party a Sublicense.

1.71 “**Sublicense Revenue**” means all consideration received by a Party or its Affiliates from a Sublicensee in consideration for a sublicense, license or similar right granted to such Sublicensee, pursuant to a written agreement, to Develop, manufacture or commercialize the Product (each such grant, a “**Sublicense**”), but excluding: (a) consideration received by such Party or its Affiliates as payments for actual direct costs for performing Development activities or commercialization activities with respect to the Product undertaken by such Party or its Affiliates for, or in collaboration with, such Third Party(ies) or their Affiliates; (b) consideration received by such Party or its Affiliates from such Third Party(ies) or their Affiliates as the purchase price for such Party’s or any of its Affiliates’ debt or equity securities, except that consideration that exceeds the fair market value of such debt or equity securities shall not be so excluded; (c) consideration received by such Party or its Affiliates from such Sublicensee for such Sublicensee’s purchase of Product that are not in excess of the Manufacturing Cost therefor; (d) any reimbursement of expenses or cost share; and (e) amounts received in consideration for the acquisition of such Party or Affiliate, or all or substantially all of the assets of such Party or Affiliates related to this Agreement (whether by merger, sale of stock, or sales of assets or otherwise).

1.72 “**Sublicensee**” means (a) with respect to Mylan, any Third Party to which Mylan has granted the right to commercialize the Product within the scope of the license granted to Mylan hereunder and (b) with respect to Revance, any Third Party to which Revance has granted the right to commercialize the Product in a Reverted Country. For clarity, Sublicensee shall exclude any contract manufacturer or other Third Party acting solely on behalf of a Party or its Affiliates and not on its own behalf.

1.73 “**Successful Completion**” means, with respect to a Clinical Trial, that such Clinical Trial [\*].

1.74 “**Terminated Country**” means any country in which this Agreement has been terminated in accordance with Section 14.2, 14.3, 14.4, or 14.5. For clarity, a “**Terminated Country**” shall not include a Reverted Country; provided that a termination of this Agreement in its entirety pursuant to any of the Sections set forth above in this Section 1.74 shall result in all countries (including all Reverted Countries) in the world (excluding Japan) being deemed Terminated Countries.

1.75 “**Territory**” means, with respect to Mylan, the Mylan Territory, and with respect to Revance, the Revance Territory.

1.76 “**Third Party**” means any Person other than Revance, Mylan and their respective Affiliates.

1.77 “**United States**” or “**U.S.**” means the United States of America.

1.78 “**U.S. Annual Product Revenues**” means total Net Sales of Product sold by Mylan or its Affiliates or their respective Sublicensees in the U.S. in a particular calendar year.

1.79 **“Valid Claim”** means a claim of any issued and unexpired patent or any patent application within the Licensed Intellectual Property Rights that has not been held invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed.

1.80 **Additional Definitions.** Each of the following terms shall have the meaning described in the corresponding Section of this Agreement indicated below:

<b>Term</b>	<b>Section</b>	<b>Term</b>	<b>Section</b>
Acquiring Entity	16.8(c)(iv)	<b>Error! Reference source not found.</b>	16.8(c)(i)
Agreement	Preamble	Mylan CMO	7.2(b)
Additional Development Costs	5.3(f)	Mylan Data	14.6(b)(i)
Anti-Corruption Laws	11.3(a)	Mylan Indemnitees	13.1(a)
Arbitrator	4.8	Mylan Inventions	10.3
Change of Control	16.8(c)(iv)	Party or Parties	Preamble
CMO	7.2(b)	Patent Infringement Notice	10.5
Co-Chair	4.3	Payer	9.3(c)
Committee	4.1	Pharmacovigilance Agreement	6.5
Competing Product	2.4(a)	Prior CDA	12.1
Confidential Information	12.1	Public Announcement Matters	12.5
Continuation Decision	5.2(c)	Quality Agreement	7.2(a)
Continuation Notice	5.2(c)	Receiving Party	12.1
Continued Development Cost Cap	5.3(d)(i)	Recipients	12.2
Cost Overrun	5.3(d)(ii)	Reconciliation Report	Exhibit 1.31
Covered Third Party	16.8(c)(ii)	Resulting Products	5.3(f)
Defensive Action	10.2(a)	Revance	Preamble
Development Budget	5.3(b)	Revance Acquiree	16.8(b)
Development Plan	5.3(b)	Revance Acquisition	16.8(b)
Disclosing Party	12.1	Revance CMO	7.2(b)
Dispute	15.1	<b>Error! Reference source not found.</b>	16.8(b)
Dispute Notice	4.5	<b>Error! Reference source not found.</b>	16.8(c)
Equipment	7.3(b)	Revance Data	14.6(c)(i)
Excess Revance Costs	5.2(b)	Revance Indemnitees	13.1(b)
Existing Revance Products	1.60	Reverted Country	7.1(c)
Facility	7.3(a)	Royalty Holiday	Exhibit 1.31
FCPA	11.3(a)	Royalty Report	Exhibit 1.31
FDA Advisory Milestone Payment	Exhibit 1.31	Sale Transaction	16.8(a)
FDA Advisory Package	4.1(f)	Second Tier Markets	7.1(c)
FDA Minutes	5.2(a)	Selling Party	1.54
Force Majeure	16.5	Senior Executives	4.5
Indemnify	13.1(a)	Signing Date	Preamble
Initial Development Cost Cap	5.2(b)	Subcommittee	4.1
Initial Development Cost Report	Exhibit 1.31	Supply	7.2(a)
Initial Development Plan	5.2(a)	Supply Terms	7.2(a)
Inventions	10.3	Term	14.1

<b>Term</b>	<b>Section</b>	<b>Term</b>	<b>Section</b>
Joint Patent	10.3	Third-Party Acquirer	16.8(b)
JSC or Joint Steering Committee	4.1	Third-Party Claim	13.1(a)
JSC Term	4.2	Tier 1 Revenues	Exhibit 1.31
Lease Transfer Notice	7.3(b)	Trade Control Laws	11.4(a)
Legal Expenses	10.2(c)	UKBA	11.3(a)
Legal Strategy Costs	10.1(a)	Upfront Payment	Exhibit 1.31
Liabilities	13.1(a)	VAT	9.3(b)
Mylan	Preamble		

1.81 **Interpretation.** The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (ii) the word “or” shall have its inclusive meaning of “and/or;” (iii) the word “notice” shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); (v) provisions that require that a Party, the Parties or any Committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing; (vi) words of any gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof; and (ix) neither Party shall be deemed to be acting “on behalf of” or “under the authority of” the other Party.

## ARTICLE 2

### GRANT OF RIGHTS AND EXCLUSIVITY

#### 2.1 License Grants to Mylan.

(a) **License.** Subject to the terms and conditions of this Agreement, Revance hereby grants to Mylan an exclusive license, including the right to grant and authorize sublicenses, under the Licensed Technology Rights to develop, make and have made (subject to Article 7 of this Agreement and the terms of the Supply Agreement), use, sell, offer for sale, import and otherwise Exploit the Product, in each case, in the Mylan Territory. For clarity, Revance will (i) retain rights under the Licensed Technology Rights to complete its Development and manufacturing responsibilities with respect to the Product in the Mylan Territory hereunder in accordance with this Agreement and the Ancillary Agreements and (ii) retain the rights under the Licensed Technology Rights to Exploit the Product in the Revance Territory and to Exploit any product that is not a Product anywhere in the world. Notwithstanding the foregoing to the contrary, Mylan shall not have the right to manufacture (or have manufactured) Biological Active Substance.

(b) **Ex-Territory License.** Subject to the terms and conditions of this Agreement, Revance hereby grants to Mylan a non-exclusive license, including the right to grant and authorize sublicenses, under the Licensed Technology Rights to Develop and make and have made (subject to Article 7 of this Agreement and the terms of the Supply Agreement), import and use the Product, in each case, outside the Mylan Territory for purposes of filing for Marketing Authorization, selling, offering for sale and otherwise Exploiting the Product, in each case, in the Mylan Territory.

(c) **Retained Rights.** Notwithstanding the exclusive license granted to Mylan pursuant to Section 2.1(a), Revance retains a non-exclusive right, under the Licensed Technology Rights, to Develop, make, or have made the Product in the Mylan Territory solely for purposes of filing for Marketing Authorization, selling, offering for sale and otherwise commercializing the Product, in each case, in the Revance Territory.

## 2.2 License Grants to Revance.

(a) **License in Revance Territory.** Subject to the terms and conditions of this Agreement, Mylan hereby grants to Revance a non-exclusive license, including the right to grant and authorize sublicenses, under the Mylan Technology Rights to Exploit the Product in the Revance Territory.

(b) **Ex-Revance Territory License.** Mylan hereby grants to Revance a non-exclusive license, including the right to grant and authorize sublicenses, under the Mylan Technology Rights to Develop, make, or have made the Product in the Mylan Territory solely for purposes of filing for Marketing Authorization, selling, offering for sale and otherwise Exploiting the Product, in each case, in the Revance Territory.

(c) **Collaboration Data.** To the extent that Revance or its Affiliates or their Sublicensees utilize the Collaboration Data, or any Regulatory Filings, Marketing Authorizations, regulatory communications or Product-Related Data provided by Mylan pursuant to Section 5.5, to Exploit the Product in [\*], Revance shall pay Mylan a [\*] royalty on Net Sales of the Product in Japan until Revance has paid to Mylan [\*] in the aggregate in royalties under this Section 2.2(c). Except as expressly set forth in this Agreement, Revance and its Affiliates shall not use, or grant any Third Party rights to use, any Collaboration Data for purposes of, directly or indirectly, developing, manufacturing or commercializing the Product or any Competing Product.

2.3 **Territory Integrity.** Each Party agrees that, neither it, nor any of its Affiliates or Sublicensees, as applicable, will directly or indirectly develop, file for Marketing Authorization with respect to, or make, have made, use, sell, offer for sale, promote import and otherwise commercialize, the Product outside of its respective Territory, except, with respect to Revance in the Mylan Territory, for or through Mylan and its designees in accordance with the terms and conditions of this Agreement and the Supply Agreement and except as expressly provided in Sections 2.1(b) and 2.2(b); provided that the foregoing shall not serve as a non-compete to preclude or limit Mylan from developing, manufacturing or commercializing a Product in the Revance Territory independent of Revance and without use of Revance or its Affiliate's interest in the Licensed Technology Rights.

## 2.4 Exclusivity for the Product in the Mylan Territory.

(a) The Parties acknowledge that the grant of rights and licenses hereunder is intended to provide exclusive rights to Mylan for the development, manufacture and commercialization of the Product for and in the Mylan Territory. Accordingly, Revance shall not, and shall cause its Affiliates not to, directly or indirectly, develop, manufacture or commercialize (including seek Marketing Authorization for), or authorize or otherwise assist any Third Party in developing, manufacturing or commercializing (including by providing access or right of reference to Licensed Technology Rights or Regulatory Filings of Revance or its Affiliates), or supply to any Third Party, [\*] (each, a “**Competing Product**”) in the Mylan Territory, or develop, manufacture or import any Competing Product outside the Mylan Territory for purposes of developing or commercializing any Competing Product in the Mylan Territory, in each case other than the Product for or through Mylan in accordance with this Agreement or the Ancillary Agreements or as otherwise permitted under Section 2.1(c).

(b) If a court determines that the foregoing restrictions are too broad or otherwise unreasonable under Applicable Law, the Parties hereby agree to revise the foregoing restrictions to include the maximum restrictions allowable under Applicable Law. Each of the Parties acknowledges, however, that this Section 2.4 has been negotiated by the Parties and that the restriction is reasonable in light of the circumstances pertaining to the Parties.

2.5 **No Other Rights.** Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted hereunder, whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. ALL RIGHTS WITH RESPECT TO TECHNOLOGY, KNOW-HOW OR INTELLECTUAL PROPERTY RIGHTS THAT ARE NOT SPECIFICALLY GRANTED HEREIN ARE RESERVED TO THE OWNER OF SUCH TECHNOLOGY, KNOW-HOW OR INTELLECTUAL PROPERTY RIGHTS.

## ARTICLE 3

### AFFILIATES AND THIRD PARTY DESIGNEES

The Parties shall have the right to have one or more of their respective Affiliates, or Third Party designees, exercise any or all of such Party’s rights or perform any or all of such Party’s responsibilities under this Agreement on its behalf, in each case subject to the terms and conditions of this Agreement; *provided* that, except in the case of an assignment of this Agreement in its entirety made by a Party in accordance with Section 16.8, such Party shall remain liable hereunder for the prompt performance of all of its obligations hereunder.

## ARTICLE 4

### GOVERNANCE

4.1 **Joint Steering Committee.** Within thirty (30) calendar days of the Effective Date, the Parties will establish a joint steering committee (the “**JSC**” or “**Joint Steering Committee**”) for the overall coordination and oversight of the Parties’ development, manufacture and regulatory activities with respect to the Product under this Agreement. The JSC may from time to time establish one or more subcommittees (each, a “**Subcommittee**”), to perform certain duties and exercise certain powers of the

JSC as expressly delegated by the JSC to such Subcommittee (each of the JSC and any such Subcommittee is referred to herein as a “Committee”). The role of the Joint Steering Committee shall be:

(a) to review, coordinate, and discuss the overall strategy for seeking, obtaining and maintaining Marketing Authorizations of the Product in the Mylan Territory;

(b) to review and approve any Development Costs associated with the Initial Development Plan in excess of the Initial Development Cost Cap, pursuant to Section 5.2(b) below;

(c) to review and approve the Development Plan (including the protocols for any Clinical Trials included therein) and Development Budget, and any amendments thereto, pursuant to Section 5.3(b) below;

(d) to provide a forum for the Parties to exchange Product-Related Data and other information with respect to matters pertaining to and status of the development and manufacture of the Product as set forth hereunder;

(e) to provide a forum to keep the Parties informed as to the strategic direction for the development, manufacturing and commercialization of the Product, including strategies for obtaining, maintaining and enforcing patent protection for the Product, and strategies for Legal Clearance Activities, as set forth hereunder;

(f) to determine the data necessary to support, and develop the development plan for the Product to be included in, the briefing package to be submitted to the FDA for the Product in advance of the FDA Scientific Advice Meeting (such briefing package, the “FDA Advisory Package”);

(g) to review, approve and oversee the implementation of a continuous improvements program developed by the Parties to reduce Manufacturing Costs;

(h) to make decisions with respect to matters referred to it from the Subcommittees that are within the scope of its decision-making authority; and

(i) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth hereunder or otherwise determined in writing by the Parties.

4.2 **Term of the JSC.** The JSC will remain in effect during the Term, unless the Parties otherwise mutually agree in writing (the “JSC Term”). Upon expiration of the JSC Term, the JSC and all Subcommittees will be disbanded. Thereafter during the Term, (a) any information, reports and materials that are required under this Agreement to be provided to the JSC shall be provided to each Party directly, and (b) decisions and actions delegated to the JSC under this Agreement will be performed directly by authorized representatives of the Parties.

4.3 **Committee Membership.** The JSC and any Subcommittee shall each be comprised of an equal number of representatives from each of Mylan and Revance, selected by such Party, and either Party may replace its respective Committee representatives at any time with prior notice to the other Party, *provided* that such replacement is of comparable authority and, if appropriate, scope of functional responsibility within that Party’s organization as the individual he or she is replacing. The number of



such representatives to the JSC shall be three (3) for each of Mylan and Revance, or such other number as the Parties may agree, with one (1) such member for each Party having decision-making authority on behalf of such Party within the scope of the JSC's responsibilities. The Parties' initial JSC members are set forth on Exhibit 4.3. Without limiting the foregoing, each Party shall appoint by notice to the other Party one of its members to the JSC to co-chair the meetings of the JSC (each, a "**Co-Chair**"). Each Co-Chair, working together (directly or through their designees), shall (a) coordinate and prepare the agenda and ensure the orderly conduct of the JSC's meetings; (b) attend (subject to below) each meeting of the JSC; and (c) prepare and issue minutes of each meeting within fifteen (15) Business Days thereafter accurately reflecting the discussions and decisions of the JSC at such meeting. Such minutes from each JSC meeting shall not be finalized until the Co-Chair from each Party has reviewed and approved the accuracy of such minutes in writing. The Co-Chairs shall solicit agenda items from the other JSC members and provide an agenda along with appropriate information for such agenda reasonably in advance (to the extent possible) of any meeting. In the event the Co-Chair or another member of the JSC from either Party is unable to attend or participate in any meeting of the JSC, the Party who designated such Co-Chair or member may designate a substitute Co-Chair or other representative for the meeting.

#### 4.4 **Joint Steering Committee Meetings.**

(a) **Conduct.** The Joint Steering Committee shall hold at least four (4) meetings per year at such times as it elects to do so, with approximately one (1) such meeting held per calendar quarter, *provided* that the JSC shall have the right to change the frequency of such meetings. Meetings of the Joint Steering Committee shall be effective only if at least one (1) representative of each Party is present or participating. The Joint Steering Committee may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference, as agreed by the Parties. The location of any in-person meetings shall alternate between the sites of the two (2) Parties. With the prior consent of the other Party's representatives (such consent not to be unreasonably withheld or delayed), each Party may invite non-member employees of such Party to participate in the discussions and meetings of the Joint Steering Committee, *provided* that such participants shall have no vote and shall be subject to the confidentiality provisions set forth in Article 12 below. A Party may also call a special meeting of the JSC by providing at least ten (10) Business Days' prior written notice to the other Party if such Party reasonably believes that a matter within the JSC's authority must be addressed prior to the next scheduled meeting, in which event such Party shall provide the other Party a proposed agenda, together with such meeting request. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Joint Steering Committee.

(b) **Progress Report.** At each meeting of the JSC, each Party shall summarize to the JSC the progress of the Development and manufacturing activities performed by or under authority of such Party or its Affiliates with respect to the Product in the Mylan Territory, including pursuant to the Development Plan, during the period since the last meeting of the JSC. Without limiting the foregoing, Revance will also summarize to the JSC the progress of its development of the Product outside of the Mylan Territory. Each summary shall include all material decisions and actions relating to the development of, or filing of any Regulatory Filing or obtaining or maintaining any Marketing Authorization, including summaries of resulting Product-Related Data generated during such period. Mylan shall keep Revance reasonably informed with respect to its commercialization activities for the Product in the Mylan Territory by providing updates on a regular basis at JSC meetings, provided that Mylan shall cease to provide such updates if so requested by Revance.

4.5 **Committee Decision Making.** Decisions of each Committee shall be made by consensus, with each Party having one (1) vote; *provided* that the Subcommittees shall not have decision-making authority, other than to the extent reasonably necessary to determine how to conduct day-to-day activities in accordance with the Initial Development Plan, the Development Plan and this Agreement. The Parties shall work in good faith to reach consensus on matters within the scope of each Committee's decision-making authority. In the event a Subcommittee fails to reach consensus with respect to a particular matter within its authority, then upon request by either Party such matter shall be referred to the JSC for resolution. In the event that the JSC fails to reach consensus with respect to a matter within its decision-making authority, then either Party may, by written notice to the other Party (the "**Dispute Notice**"), have such matter referred to an executive of each Party who is senior in rank and authority to such Party's JSC representatives and has the right to bind such Party with respect to such matter ("**Senior Executives**") who shall meet promptly and negotiate in good faith to resolve such matter; *provided, however* if the Senior Executives are unable to agree with respect to any particular dispute within the scope of the JSC's decision-making authority within [\*] calendar days of the Dispute Notice, then (without recourse to the dispute resolution procedure set forth in Article 15) (a) [\*] shall have the final decision making authority with respect to all matters related to [\*], (b) [\*] shall have the final decision making authority (1) with respect to all matters related to the [\*], or (2) with respect to [\*], (c) [\*] matters shall require consensus of the Parties, and (d) disputes with respect to any matter (other than those described in clauses (a) through (c) above and as provided for in the last sentence of this Section 4.5) within the scope of the JSC's decision-making authority (excluding matters related to [\*]) may be submitted, by either Party, to arbitration in accordance with Section 4.8 for resolution, as the exclusive dispute resolution mechanism for such disputes. Notwithstanding the foregoing, [\*] shall in good faith try to [\*]. Neither Party shall have the right to cast its deciding vote in a manner that would [\*]. Further, [\*], including with respect to matters related to [\*], shall require consensus of the Parties' and if no consensus is obtained, then the status quo shall prevail until such consensus is achieved, i.e., [\*], unless and until such consensus agreement is obtained.

4.6 **Scope of Governance.** Notwithstanding the creation of the JSC or any Subcommittee, each Party shall retain the rights, powers and discretion granted to it hereunder, and no Committee shall be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. For avoidance of doubt, any decision that this Agreement provides is to be made by the Parties shall not be within the scope of the JSC's or any Subcommittee's decision-making authority. No Committee shall have the power to amend or modify this Agreement, and no decision of any Committee shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the JSC or any Subcommittee, as applicable, are only those specific issues that are expressly provided in this Agreement to be decided by such Committee. For clarity, neither (a) [\*] nor (b) [\*] shall be subject to JSC oversight; rather each of the foregoing ((a) and (b)) shall [\*].

4.7 **Day-to-Day Responsibilities.** Each Party shall be responsible for day-to-day implementation and operations of the activities hereunder for which it has or is otherwise assigned responsibility under this Agreement, *provided* that such implementation is consistent with the express terms of this Agreement or the decisions of any Committee within the scope of its authority specified herein.

4.8 **Arbitration.** If the Senior Executives are unable to reach consensus within [\*] days of a matter within the JSC's decision-making authority being referred to them, which matter is not subject to Mylan's or Revance's final decision-making authority and which does not require consensus under Section 4.5, the final decision with respect to such matter will be made by a single, mutually acceptable Third Party arbitrator (the "**Arbitrator**"). Either Party can initiate such arbitration on [\*] calendar day's written notice to the other Party. The arbitration shall be conducted by [\*] pursuant to [\*] then in effect, in [\*], and shall be subject to the following:

(a) **Fees.** The fees of associated with the [\*] any such arbitration shall be shared equally by the Parties and, thereafter, shall be borne by the Party that initiates such arbitration, in each case unless otherwise allocated by the Arbitrator.

(b) **Confidentiality.** The arbitration proceeding shall be confidential. Except as required by Applicable Law, no Party shall make (or instruct [\*] or the Arbitrator to make) any public announcement with respect to the proceedings or decision of the Arbitrator without prior written consent of each other Party. The existence of a dispute submitted to arbitration hereunder, and the outcome, shall be kept in confidence by the Parties, their Affiliates, their counsel, insurers and re-insurers, accountants and auditors, and any Person necessary to the conduct of the proceeding. The confidentiality obligations shall not apply if (i) disclosure is required by Applicable Law or (ii) to the extent necessary to enforce the rights arising out of the award.

(c) **Findings of Arbitrator.** The decision of the Arbitrator will be final and binding on the Parties. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party.

(d) **Injunctive Relief.** Notwithstanding the foregoing, any Party has the right to apply to any court of competent jurisdiction for interim relief necessary to preserve the Party's rights until the Arbitrator is appointed. After appointment of the Arbitrator, the Arbitrator shall have the exclusive jurisdiction to consider applications for interim relief.

## ARTICLE 5

### PRODUCT DEVELOPMENT

5.1 **General.** Subject to the oversight of the JSC and collaboration with the other Party, (a) Revance will be primarily responsible for leading (i) non-clinical Development and CMC-related regulatory preparation activities for the Product in the Mylan Territory set forth in the Development Plan, (ii) subject to Section 5.3(c), the implementation of Clinical Trials of the Product in North America conducted prior to submission of the first MAA to the FDA pursuant to the Development Plan, (iii) subject to Section 7.2, manufacturing activities for the Mylan Territory, including clinical (where applicable) and commercial supply of the Biological Active Substance and, if applicable, the Product to Mylan for the Mylan Territory; and (b) Mylan will be primarily responsible for leading, with respect to the Mylan Territory (i) the implementation of Clinical Trials outside of North America (subject to Section 5.3(c)) and Clinical Trials in North America after submission of the first MAA to the FDA, and related activities, for the Product, (ii) communications with Regulatory Authorities regarding the Product following the FDA Scientific Advice Meeting, including making all required Regulatory Filings (*provided*, that Revance shall file the IND with respect to Clinical Trials of the Product that it is conducting under the Development

Plan with the FDA and may file a drug master file with the FDA), and (iii) any litigation arising out of the MAA for, or launch or ongoing commercialization of, the Product in the Mylan Territory. Each Party shall (directly and/or through one or more Affiliates and/or Sublicensees) use Commercially Reasonable Efforts to conduct the activities related to Development of the Product for which it is responsible under the Development Plan. The Party that is not responsible for leading a particular Development activity with respect to the Product under the Development Plan shall use Commercially Reasonable Efforts to assist the lead Party with respect to such activities, including as reasonably requested by the lead Party. For clarity, Revance retains the sole right to conduct Development in the Revance Territory (subject to the right of Mylan pursuant to Section 2.1(b)). Without limiting Revance's CMC-related regulatory preparation responsibilities, Revance shall be responsible for preparing the CMC and clinical modules of the MAA for the Product in a manner suitable for filing with the FDA and EMA, in compliance with Applicable Laws in the U.S. and Europe. Revance, at the request of Mylan, shall use Commercially Reasonable Efforts to prepare the CMC Module 3 of the MAA for the Product elsewhere in the Mylan Territory; *provided*, that Mylan shall reimburse Revance for its reasonable costs incurred in conducting such activities and Mylan acknowledges that Revance will not be required to conduct activities outside of the U.S. and Europe with respect thereto.

## 5.2 Initial Development.

(a) **Initial Development Plan.** Revance will retain primary responsibility, at Revance's expense (subject to the cap described in Section 5.2(b) below) and in collaboration with Mylan, for conducting the further Product characterization and Development activities necessary to prepare for and conduct an FDA Scientific Advice Meeting, as set forth on Exhibit 5.2 (the "**Initial Development Plan**"). Revance shall use Commercially Reasonable Efforts to complete the activities set forth in the Initial Development Plan in accordance with this Agreement and Applicable Law, and shall maintain complete and accurate records of such activities, which shall be subject to audit by Mylan in accordance with Section 9.4. All briefing packages and other materials submitted to the FDA in advance of the FDA Scientific Advice Meeting, including the FDA Advisory Package for the Product as a Biosimilar, shall be subject to review and approval by the JSC prior to submission to the FDA. Revance shall coordinate with Mylan with respect to scheduling the FDA Scientific Advice Meeting and shall provide Mylan with written notice of the timing for the FDA Scientific Advice Meeting within five (5) days of such meeting being scheduled. Mylan shall participate in all preparatory meetings for the FDA Scientific Advice Meeting, and at least two (2) representatives from Mylan shall attend and participate in the FDA Scientific Advice Meeting. Revance shall provide Mylan with a copy of Revance's meeting minutes from the FDA Scientific Advice Meeting for review and comment prior to finalizing such minutes. Further, Revance shall provide Mylan with the FDA's final minutes from the FDA Scientific Advice Meeting (the "**FDA Minutes**") within two (2) Business Days of Revance's receipt of such minutes.

(b) **Initial Development Cost Cap.** Revance shall bear its own costs and expenses in conducting the Initial Development Plan. Notwithstanding the foregoing but subject to the remainder of this Section 5.2(b), once Revance has incurred [\*] in Development Costs (the "**Initial Development Cost Cap**"), the Parties shall share Development Costs equally in accordance with Section 5.3(d). Revance shall provide Mylan with quarterly reports of its Development Costs in accordance with paragraph 6 of the Financial Exhibit. In the event that the Development Costs incurred in connection with the Initial Development Plan exceed, or Revance anticipates that such Development Costs will exceed, the Initial Development Cost Cap by more than [\*], any such excess Development Costs shall

be subject to JSC approval prior to being subject to the sharing described in Section 5.3(d). For clarity, if the JSC does not approve of any increase in Development Costs associated with Development activities necessary to prepare for and conduct the FDA Scientific Advice Meeting, in excess of the Initial Development Cost Cap, Revance shall have the right to continue to carry out such Development under the Initial Development Plan, *provided* that Revance shall bear any of its costs in excess of the Initial Development Cost Cap (any such increased costs attributable solely to new or increased Development activities necessary to prepare for an FDA Scientific Advice Meeting, the “**Excess Revance Costs**”). Such Excess Revance Costs are subject to reimbursement as provided in clause (c) below.

(c) **Continuation Decision.** Mylan shall make a continuation decision as to whether to continue the Development and commercialization of the Product beyond the Initial Development Plan pursuant to this Agreement, as set forth in this Section 5.2(c) (the “**Continuation Decision**”) following receipt of the FDA Minutes, including feedback on the FDA Advisory Package, and finalization of the Development Plan in accordance with Section 5.3(b). Mylan shall notify Revance in writing within [\*] Business Days after [\*] of Mylan’s decision to either continue or not to continue the Development and commercialization of the Product pursuant to this Agreement (the “**Continuation Notice**”). If Mylan’s Continuation Decision is that it will continue Development and commercialization of the Product pursuant to this Agreement, Revance shall submit an invoice to Mylan for the FDA Advisory Milestone Payment (plus [\*] any Excess Revance Costs) upon receipt of the Continuation Notice. If Mylan’s Continuation Decision is that it will not continue Development and commercialization of the Product pursuant to this Agreement, either Party may terminate this Agreement upon written notice to the other Party provided within [\*] days of receipt of Mylan’s Continuation Decision; *provided* that if neither Party terminates pursuant to this sentence, the Parties shall promptly meet to discuss in good faith whether there is a path forward for the Product in the Mylan Territory hereunder, including any necessary changes to this Agreement, the Development Plan and Development Budget. The Parties agree that prior to the commencement of the [\*]-Business Day period provided for above, the Parties shall, collaborate on (i) development of a preliminary strategy for Legal Clearance Activities for consideration by the JSC in creating the Development Plan and (ii) development of a Development Plan that includes a detailed regulatory strategy for the Product in the U.S. and Europe, in accordance with Section 5.3(b) below.

### 5.3 **Continued Development.**

(a) **Collaboration.** Following Mylan’s payment of the FDA Advisory Milestone Payment (and [\*] Excess Revance Costs, if any) to Revance, the Parties shall continue to collaborate in all respects to Develop the Product as necessary to obtain Marketing Authorization for the Product in the U.S. and Europe in accordance with the Development Plan. Each Party will use Commercially Reasonable Efforts to perform, and to assist the other Party in the performance of, its development and regulatory activities with respect to the Product in the U.S. and Europe in accordance with the Development Plan (including all timelines set forth therein), this Agreement and Applicable Law, and shall maintain complete and accurate records of such activities, which shall be subject to audit in accordance with Section 9.4 of this Agreement and paragraph 6 of the Financial Exhibit. As between the Parties, each Party shall bear all of the costs and expenses incurred in connection with any of the activities performed by such Party (itself or through its Affiliates or contractors) in the course of the Development of the Product for the U.S. and Europe, subject to Section 5.2(b) and the sharing set forth in Section 5.3(d) and Section 5.3(e) below.

(b) **Development Plan.** Within [\*] days of [\*], the Parties shall, through the JSC, complete the preparation of an initial development plan for the Product that sets out the Development activities to be conducted by or under the authority of each Party for Developing, and obtaining Marketing Authorization(s) for, the Product in the U.S. and Europe (the “**Development Plan**”), as well as a reasonably detailed budget setting forth the Development Costs for such activities related to Development of the Product for the U.S. and Europe (the “**Development Budget**”). The allocation of activities between the Parties in the Development Plan shall be consistent with Section 5.1. In the event the Parties are unable to reach consensus with respect to the Development Plan and Development Budget within such [\*]-day period, despite negotiating in good faith, Mylan shall not be obligated to make the FDA Advisory Milestone Payment and, if Mylan does not pay the FDA Advisory Milestone Payment, either Party may terminate this Agreement upon written notice to the other Party. At least once every calendar quarter until Marketing Authorization has been received in the U.S. and Europe, each Party shall submit to the JSC any updates to its proposed activities under the Development Plan, including any material modifications or additions thereto, for the JSC’s review and approval and coordination of the Parties’ activities with respect to the Product as set forth hereunder. The Development Plan shall contain the following information with respect to the Product in the U.S. and Europe: (i) scope and timelines for the conduct of all Development activities and studies (including any studies for the applicable approvals of labeling, price and reimbursement) designed to support Marketing Authorization of the Product; (ii) estimated timing of meetings with Regulatory Authorities for the Product; and (iii) target schedules for achieving milestones in developing the Product. The Parties acknowledge and agree that Revance may conduct certain of its Development activities under the Development Plan, which are intended to support the MAA for the Product in the U.S., elsewhere in North America, and the associated Development Costs shall be shared in accordance with the Development Budget and Section 5.3(d).

(c) **Protocols and Clinical Trials.** The protocol for each Clinical Trial to be performed by or on behalf of such Party or its Affiliates or Sublicensees with respect to the Product for the U.S. and Europe, any related statistical analysis plans, and any material modification of such protocols or plans from time to time, in each case to be included in the Development Plan, shall be subject to review and approval of the JSC.

(d) **Development Costs.**

(i) **Continued Development Cost Cap.** Subject to Section 5.2(b), any Development Costs incurred with respect to Development of the Product for the Mylan Territory as a whole, or for the U.S. and Europe, in each case in accordance with the Development Plan and Development Budget will be shared equally by the Parties. Each Party will report such Development Costs to the other Party in accordance with paragraph 6 of the Financial Exhibit. The Parties anticipate that the total Development Costs, to be incurred after completion of the FDA Scientific Advice Meeting, will be approximately [\*] (the “**Continued Development Cost Cap**”). In the event that either Party anticipates that the aggregate Development Costs to be incurred after completion of the FDA Scientific Advice Meeting to obtain Marketing Authorizations for the Product throughout the Mylan Territory will be in excess of the Continued Development Cost Cap, such Party shall request a meeting of the JSC, pursuant to which the JSC shall agree upon any necessary amendments to the Development Plan and determine the allocation of such excess Development Costs; *provided* that the Parties shall, in any event, hold such a JSC meeting when the aggregate Development Costs reported pursuant to paragraph 6 of the Financial Exhibit reach [\*].

(ii) **Cost Overrun.** In no event shall either Party be obligated to incur Development Costs under the Development Plan that are in excess of its respective share of the Development Costs set forth in the then-current Development Budget, unless and until agreement is reached by the JSC with respect to the sharing of such excess Development Costs. Without limiting the foregoing, if either Party anticipates that its quarterly Development Costs that are subject to sharing hereunder may exceed the corresponding portion of the Development Budget for such calendar quarter (a “**Cost Overrun**”), then, together with its quarterly report set forth in paragraph 6 of the Financial Exhibit, such Party will promptly give written notice to the other Party of the anticipated Cost Overrun, including an explanation for such Cost Overrun. Subject to this Section 5.3, the Parties will share Cost Overruns in a given calendar quarter in accordance with clause (i) above and paragraph 6 of the Financial Exhibit to the extent such Cost Overruns do not exceed [\*] of those set forth in the then-current Development Budget for such calendar quarter; *provided* that such Cost Overrun does not cause, and is not anticipated to cause, the Parties to exceed the Development Budget for such calendar year. If such Cost Overruns exceed the Development Budget for such calendar quarter by more than [\*] or are anticipated to exceed the Development Budget for such calendar year, the Parties shall, through the JSC, meet promptly to discuss the reasons for such Cost Overruns and their impact on the annual Development Budget. The Cost Overrun mechanism is implemented as a tool to monitor and effectively manage quarterly variations in Development Costs for timing differences. It does not provide approval to increase the Development Budget.

(e) Notwithstanding the foregoing, Mylan shall have the right to control any activities with respect to, and shall bear any Development Costs specific to, obtaining Marketing Authorization for the Product in countries in the Mylan Territory outside of the U.S. and Europe.

(f) In the event that, despite negotiating in good faith, the JSC fails to reach consensus with respect to Development activities for the Product for the U.S. or Europe, which are proposed by a Party to be included in the Development Plan and are reasonably necessary to obtain the MAA for the Product in such portion of the Mylan Territory, such Party may conduct the proposed activities; provided that the results of any such activities generated by Mylan shall be, and hereby are, included in the Mylan Technology Rights, and the results of any such activities generated by Revance shall be, and hereby are, included in the Licensed Technology Rights. The Party performing such Development activities shall initially solely bear any Development Costs with respect thereto (“**Additional Development Costs**”) and shall report such Additional Development Costs to the other Party in accordance with paragraph 6 of the Financial Exhibit. If the Product that is the subject of such additional Development activities receives Marketing Authorization in the U.S. or Europe, such Party shall be reimbursed for [\*] of its reasonable Additional Development Costs through an adjustment to the royalty owed to Revance with respect to such country(ies), pursuant to paragraph 5 of the Financial Exhibit, on Net Sales of the Product that is approved based on an MAA incorporating the results of such Development activities (a “**Resulting Product**”), as follows.

(i) In the event that Mylan incurs Additional Development Costs and the Resulting Product is approved, Mylan shall reduce the royalty owed to Revance pursuant to paragraph 5 of the Financial Exhibit with respect to Net Sales of such Resulting Product in the portion of the Mylan Territory (U.S. or Europe) for which such Additional Development Costs were incurred, by [\*] until Mylan has recouped [\*] of such Additional Development Costs based on such royalty reduction.

(ii) In the event that Revance incurs Additional Development Costs and the Resulting Product is approved, Mylan shall increase the royalty owed to Revance pursuant to Article 5 of the Financial Exhibit with respect to Net Sales of such Resulting Product in the portion of the Mylan Territory (U.S. or Europe) for which such Additional Development Costs were incurred, by [\*] until Revance has recouped [\*] of such Additional Development Costs based on such royalty increase.

5.4 **Branded Alternative.** At any point within [\*] days following Mylan's Continuation Decision not to continue the Development and commercialization of the Product pursuant to this Agreement due to FDA feedback that a biosimilar pathway is not feasible, Mylan may, upon written notice to Revance delivered within such [\*]-day period, elect to enter into good faith discussions with Revance with respect to a new collaboration to develop and commercialize a branded biologic product incorporating the Biological Active Substance. Upon receipt of such written request, Revance will enter into good faith discussions with Mylan with respect to a new agreement for a period of [\*] months. If the Parties are unable to finalize a definitive agreement within such [\*]-month period, Mylan may request, and the Parties shall hold, a meeting of each Party's CEOs to discuss the open matters. If, after [\*] Business Days following such meeting, the Parties are still unable to finalize a definitive agreement, Revance shall have no further obligation to continue negotiations regarding such an agreement.

#### 5.5 **Information Sharing; Rights of Reference.**

(a) **Regulatory Materials.** As reasonably requested during the Term for purposes of obtaining Marketing Authorization for the Product in each Party's respective Territory in accordance with this Agreement, each Party shall provide to the other Party true and complete copies of any Regulatory Filings and Marketing Authorizations and other regulatory communications made or received by such Party with respect to the Product or the Biological Active Substance for the Product (or, to the extent required by any Regulatory Authority, any other product containing the Biological Active Substance as an active ingredient, generated by or on behalf of, or received by, such Party or its Affiliates); provided that Revance may not request or use any such Regulatory Filings, Marketing Authorizations or communications from Mylan for purposes of obtaining Marketing Authorization for any Competing Product. Without limiting the foregoing, each Party shall, upon request, provide the other Party (or its designees) with sufficient rights to reference and use any such Regulatory Filings in connection with its or its designees' activities hereunder, including providing the appropriate authorizations to such Regulatory Authority(ies) allowing such Party (or its designees) the right to reference and use any such Regulatory Filings to support any Regulatory Filing for the Product in such Party's Territory consistent with the terms and conditions of this Agreement.

(b) **Clinical Trials; Product-Related Data.** Within [\*] calendar days after the Effective Date, Revance shall provide to Mylan true and complete copies of documentation, reports and other Product-Related Data from or relating to any and all completed and on-going Clinical Trials and pre-clinical studies relating to the Product, in each case, to the extent such Product-Related Data becomes available to Revance. Additionally, each Party shall provide to the other Party true and complete copies of documentation, reports and other Product-Related Data from or relating to any and all Clinical Trials and pre-clinical studies relating to the Product for its respective Territory, in each case, to the extent such Product-Related Data becomes available to such Party. Such Product-Related Data shall include, without limitation, any and all analytical data, tiering approach information and statistical analyses (and summaries of any results in English (if such documentation and materials are not provided in English))  
Controlled



by such Party or its Affiliates relating to the Product (including original source data, reports, case report forms (CRFs) and summary literature), in each case, as such Product-Related Data becomes available to such Party. Each Party shall use the other Party's Product-Related Data disclosed pursuant to this Section 5.4(b) solely for purposes of exercising its rights and fulfilling its obligations under this Agreement.

(c) **Know-How.** Promptly after the Effective Date, without limiting any other provision herein, Revance shall provide Mylan with true and complete copies of all documentation and materials within the Licensed Know-How; each in editable electronic form, including any underlying raw data, in each case, to the extent existing in such form. During the Term, Revance shall permit Mylan (or its designees) to access, reproduce and use all Licensed Know-How, in connection with the exercise of its rights and performance of its obligations under this Agreement and shall promptly provide Mylan with copies of all Licensed Know-How generated by or on behalf of Revance or its Affiliates during the Term, to the extent not previously provided. During the Term, Mylan shall permit Revance (or its designees) to access, reproduce and use all Mylan Know-How, as is reasonably necessary in connection with the exercise of its rights and performance of its obligations under this Agreement and shall, upon Revance's request, promptly provide Revance with copies of all such Mylan Know-How generated by or on behalf of Mylan or its Affiliates during the Term.

(d) **Compliance; Language.** Each Party shall provide the other Party all Product-Related Data and other information as set forth under this Section 5.4 in a manner that is timely and compliant with all Applicable Law. All documents provided hereunder shall be in the English language. Notwithstanding anything herein to the contrary, Mylan shall not be obligated to provide Revance with any Regulatory Filings, Marketing Authorizations, communications, documentation, reports or rights of reference with respect to any Product developed or commercialized by Mylan independent of Revance and without use of Revance or its Affiliates' interest in the Licensed Technology Rights.

## ARTICLE 6

### REGULATORY MATTERS

6.1 **General.** Subject to the terms and conditions under this Article 6, Mylan (itself or through one or more Affiliates or designees) shall have the sole and exclusive right and responsibility, exercisable in its discretion, for filing with the applicable Regulatory Authorities any and all Regulatory Filings for the Product and obtaining and maintaining any and all Marketing Authorizations (including filing any amendments or supplements thereto) for the Product in the Mylan Territory; *provided*, that Revance shall file the IND with FDA for the Clinical Trials of the Product that it conducts in accordance with the Development Plan and may file a drug master file with the FDA. Revance hereby grants Mylan the right to cross reference any IND (and any drug master file) for the Product filed by Revance with the FDA and shall provide appropriate authorizations to the FDA allowing Mylan (or its designees) the right to reference and use any such IND and drug master file to support any Regulatory Filing for the Product. Without limiting the foregoing, Revance will assist Mylan in preparing and filing the MAAs and other Regulatory Filings for the Product in the Mylan Territory, as reasonably requested by Mylan, including by providing any necessary data or information and access to Revance's employees familiar with the Product or the Biological Active Substance. In connection with Mylan's filing of the first MAA with the FDA, Revance shall, upon Mylan's request, assign any INDs for the Product filed by Revance with the FDA to Mylan, and the Parties shall promptly submit all necessary notices of such assignment to the FDA. Except (in

each case) as otherwise provided under Article 5 (including Section 5.2 and 5.3), [\*] costs and expenses incurred in preparing the Regulatory Filings for the Product (provided, that [\*] the cost of any filing fees associated with the [\*]), and [\*] any filing fees associated with MAAs for the Product [\*]. For clarity, all Marketing Authorizations for the Product in the Mylan Territory will be filed by Mylan and held in Mylan or its designee's name.

## 6.2 Meetings with Regulatory Authorities.

(a) Mylan shall have the right to lead all meetings with Regulatory Authorities regarding the Product within the Mylan Territory, and shall have the sole right to interact with Regulatory Authorities with respect to the Product in the Mylan Territory, except as follows: (i) Revance shall lead meetings with Regulatory Authorities regarding its Development activities under the Initial Development Plan, including the FDA Scientific Advice Meeting and filing by Revance of certain INDs for the Product with the FDA in accordance with Section 6.1, and (ii) Revance may interact with Regulatory Authorities with respect to the Products in the Mylan Territory to the extent that Revance is required, under Applicable Law or the Supply Agreement or Quality Agreement, to interact with Regulatory Authorities as the manufacturer of the Product for the Mylan Territory. As reasonably requested by Mylan, Revance shall provide one (1) or more representatives from Revance to attend, and assist in the preparation for, meetings regarding the Product with the applicable Regulatory Authority in the Mylan Territory (as permitted by such Regulatory Authority) that are led by Mylan, subject to the confidentiality provisions set forth under Article 12 below. Mylan shall have two (2) or more representatives from Mylan attend, assist in the preparation for, and participate in the FDA Scientific Advice Meeting for the Product and any meeting with Regulatory Authorities held by Revance related to the INDs filed by Revance for the Product in the Territory, subject to the confidentiality provisions set forth under Article 12 below.

(b) Revance shall promptly provide Mylan with Revance's (as applicable) and the applicable Regulatory Authority's minutes, and any other resulting correspondence, from any meetings with Regulatory Authorities (i) regarding the Product that occurred prior to (or that occur after) the Effective Date in the Mylan Territory or (ii) to the extent the content of the resulting minutes is likely to materially affect or inform the Development or commercialization of the Product in the Mylan Territory, regarding the Products that occur outside of the Mylan Territory after the Effective Date. Mylan shall promptly provide Revance with Mylan's (as applicable) and the applicable Regulatory Authority's minutes, and any other resulting correspondence, from any meetings with Regulatory Authorities regarding the Products that occur hereunder in the Mylan Territory after the Effective Date, to the extent the content of the resulting minutes is likely to materially affect or inform the development or commercialization of the Product in the Revance Territory.

6.3 **Reporting and Review.** The Parties shall keep each other reasonably and regularly informed, directly or through the JSC of the preparation of all Regulatory Filings, Regulatory Authority review of Regulatory Filings, and Marketing Authorizations for the Product hereunder in the Mylan Territory. Revance shall keep Mylan reasonably and regularly informed of the preparation of all Regulatory Filings, Regulatory Authority review of Regulatory Filings, and Marketing Authorizations for the Product outside of the Mylan Territory during the Term.

6.4 **Regulatory Filings outside each Party's Territory.** Except in connection with each Party's (or their respective Affiliate's or Sublicensee's) exercise of rights under the license set forth in

Section 2.1(b) and 2.2(b), respectively, and as set forth in Section 6.2, (a) neither Party shall file any Regulatory Filings with Regulatory Authorities in the other Party's respective Territory for the Product licensed to Mylan hereunder without the prior written consent of the other Party, and (b) except as may be required by Applicable Law or expressly permitted pursuant to this Agreement, neither Party shall communicate with any Regulatory Authority having jurisdiction in the other Party's respective Territory regarding such a Product unless explicitly requested or permitted in writing to do so by the other Party or unless so ordered by such Regulatory Authority in the respective Territory, in which case such Party shall provide immediately to the other Party notice of such order; and in the case such Party has been so ordered by a Regulatory Authority, it shall use reasonable efforts to (i) seek the input and approval of the other Party before responding and (ii) if applicable, obtain, or assist the other Party in obtaining, a protective order or confidential treatment limiting or preventing the required disclosure. Notwithstanding the foregoing, nothing in this Agreement shall [\*] or [\*] or [\*], or [\*].

6.5 **Safety and Adverse Drug Reactions.** Promptly after the Continuation Decision, the Parties will enter into the separate safety and pharmacovigilance agreement for the Product on reasonable and customary terms consistent with industry practice (the "**Pharmacovigilance Agreement**"), which, upon execution by both Parties, will be incorporated herein by reference and will define the communication requirements, procedures, roles and responsibilities for fulfillment of pharmacovigilance obligations between the Parties with respect to the Product. Each Party shall ensure that its Affiliates and other Persons authorized thereby, as applicable, comply with all such reporting obligations. Each Party shall designate by notice to the other Party a safety liaison to be responsible for communicating with the other Party regarding the reporting of adverse events with respect to the Product. Each Party shall also promptly submit to the other Party all Product complaints of which it becomes aware. To the extent that any inconsistencies or conflicts exist between the Pharmacovigilance Agreement and this Agreement, the provisions in the body of this Agreement shall prevail, except with respect to matters related solely to safety reporting issues, in which case the Pharmacovigilance Agreement shall prevail. The Parties shall cooperate with respect to risk management activities for the Product and shall use Commercially Reasonable Efforts to address any safety issues that arise in the development or commercialization of the Product, with Mylan having the right to approve all such efforts by Revance for the Mylan Territory.

6.6 **Product Recalls.** Each Party shall promptly notify the other Party of any information received by it that could reasonably form the basis for a recall, market withdrawal or other corrective action of the Product, in sufficient detail to allow the Parties to comply with any and all Applicable Law to the extent such level of detail is available to the reporting Party. Each Party shall promptly notify the other Party of any material actions to be taken with respect to any recall or market withdrawal or other corrective action related to the Product prior to such action to permit each Party a reasonable opportunity to consult with the other Party with respect thereto. All final decisions with respect to any recall, market withdrawals or any other corrective action related to the Product in the Mylan Territory shall be made by Mylan as the Marketing Authorization holder. Each Party will keep the other Party reasonably informed with respect to any recalls, market withdrawals or other corrective action with respect to the Products in the Territory and will consider any comments from such other Party with respect thereto in good faith. [\*], in the event that Revance informs Mylan that [\*] and that a recall of such Product is necessary, then, if Mylan elects not to recall such Product, Revance shall not be responsible for any damages or liabilities with respect to Third Party claims caused by such Product.

## ARTICLE 7

### PRODUCT COMMERCIALIZATION AND MANUFACTURE

#### 7.1 Commercialization.

(a) **Commercialization Rights.** Mylan (itself or through its Affiliates, Distributors or Sublicensees) shall have the sole and exclusive right and responsibility, exercisable in its discretion but consistent with its diligence obligations under Section 7.1(b), to commercialize the Product within the Mylan Territory, including determining whether and when to launch the Product in the Mylan Territory, the pricing for the Products and how to market the Products. As between the Parties, Mylan shall bear all of the costs and expenses that it incurs in connection with any of the activities performed by Mylan (itself or through its Affiliates, Distributors or Sublicensees) in the course of the commercialization of the Product within the Mylan Territory. Mylan (itself or through its Affiliates, Distributors or Sublicensees) shall have the sole and exclusive right to determine the trademarks, trade dress, style of packaging, labeling and domain names with respect to the packaging, marketing, distribution and sales of the Product in the Mylan Territory and, as between the Parties, shall own such trademarks, trade dress, style of packaging, labeling or domain names; provided that specifications for the packaging and labeling requested by Mylan shall not require Revance to purchase or acquire additional equipment to be used to package the Product, unless otherwise agreed by Revance (in its sole discretion).

(b) **Commercial Diligence.** Mylan shall (directly and/or through one or more Affiliates, Distributors and/or Sublicensees) use Commercially Reasonable Efforts to commercialize the Product in the Mylan Territory. Notwithstanding anything herein to the contrary, and without limiting [\*], Mylan's obligations to use Commercially Reasonable Efforts to Develop or commercialize the Product in the Mylan Territory shall [\*] applicable to the Product under Applicable Law.

(c) **Reverted Countries.** Once sufficient clinical data is available to support an MAA in a country in the Mylan Territory outside of the U.S., Europe, [\*] (such remaining countries, the "**Second Tier Markets**"), and Mylan elects not to seek Marketing Authorization or commercialize the Product, itself or through one or more Affiliates, Distributors and/or Sublicensees, in such Second Tier Market, Mylan will notify Revance of such election in writing, and thereafter such Second Tier Market country shall cease to be within the Mylan Territory and shall become a "**Reverted Country**". Mylan shall transition the Product in such Reverted Country to Revance in accordance with the applicable portions of Section 14.6(b). Revance shall have the right to use the Collaboration Data for purposes of Developing and commercializing the Product in the Reverted Countries and shall have the right to commercialize the Product, itself or with or through a Third Party, in any Reverted Country; *provided that* Revance shall pay to Mylan [\*] of all Reverted Country Product Revenues from each Reverted Country on a quarterly basis, within [\*] days after the end of each calendar quarter, and shall be subject to reporting obligations to Mylan corresponding to those set forth in paragraph 5(d) of the Financial Exhibit. Such share of Reverted Country Product Revenues shall be payable, on a Reverted Country-by-Reverted Country basis, commencing on the earlier of (i) First Commercial Sale of the Product in such Reverted Country by Revance or its Affiliate and (ii) first receipt of Sublicensing Revenue from a Sublicensee in a Reverted Country, in each case continuing during the Term and thereafter in accordance with Section 14.7. For clarity, prior to the time Mylan's rights under this Section 7.1(c) become effective (i.e., before sufficient

clinical data is available to support an MAA in any country), Mylan shall nonetheless have the right to terminate unilaterally its rights to the Product in one or more Regions as set forth in Section 14.4(a).

## 7.2 Supply.

(a) **Supply Agreement; Quality Agreement.** Within six (6) months after the Effective Date, the Parties shall enter into a supply agreement (the “**Supply Agreement**”), consistent with the terms set forth on **Exhibit 7.2(a)** (the “**Supply Terms**”), pursuant to which Revance shall, itself or through its Affiliates or a Third Party contract manufacturer, manufacture and supply the Biological Active Substance and the Product exclusively to Mylan, its Affiliates or Sublicensees for sale in the Mylan Territory, subject to and in accordance with the terms and conditions set forth therein and a quality and technical agreement on reasonable and customary terms consistent with industry practice (the “**Quality Agreement**”) which shall be executed concurrently with the Supply Agreement. Revance will supply (a) the Biological Active Substance and Product to Mylan and its Affiliates for purposes of non-clinical and Clinical Trials at the transfer prices set forth in the Supply Agreement and (b) the Biological Active Substance and Product for commercial sale at its Manufacturing Cost, [\*], in each case pursuant to the Supply Agreement. Except as otherwise set forth in this Agreement or the Supply Agreement, Mylan shall purchase all of its requirements for the Biological Active Substance for use in the Product for development and commercialization in the Mylan Territory from Revance.

(b) **Manufacturing.** Mylan may elect to have Revance, a Third Party contract manufacturing organization (a “**CMO**”) selected and qualified by Revance (a “**Revance CMO**”), or a CMO or Mylan Affiliate selected by Mylan (a “**Mylan CMO**”) manufacture Product for Mylan for the Mylan Territory. For clarity, if Mylan elects for Revance to manufacture Product for the Mylan Territory, Revance shall have the right to select, qualify and manage a CMO to do so on Revance’s behalf; provided that Mylan would also have the right to qualify such Revance CMO. Mylan would have the sole right to qualify and manage any Mylan CMO with respect to the manufacture of Product for the Mylan Territory. Mylan may not make such election prior to [\*], but, with respect to an election to use a Revance CMO, Mylan must make such election within [\*] after the later of [\*] and [\*]. For clarity, if Mylan elects to have a Mylan CMO or a Revance CMO (other than through Revance) manufacture Product for Mylan for the Mylan Territory, then, Mylan shall enter into a direct contractual relationship regarding such supply, and, thereafter, Revance’s obligations to supply Mylan shall be limited to Biological Active Substance and Revance will have no further obligation to supply Product to Mylan.

(c) Revance will conduct a transfer of manufacturing Know-How as necessary or useful to enable each Revance CMO and Mylan CMO to manufacture the Product (provided, that such transfer shall be limited to [\*] and [\*]), consistent with Section 7.4 below (including the licenses and rights of reference set forth therein); provided that if Revance is qualifying a Revance CMO for manufacture of the Product at the time that Mylan requests such a transfer to a Mylan CMO, then such transfer of manufacturing Know-How to such Mylan CMO shall be delayed until the earlier of the completion of the transfer of manufacturing Know-How by Revance to the Revance CMO or [\*] from Mylan’s request to begin such transfer of manufacturing Know-How to the Mylan CMO. The Parties will discuss in good faith the benefit of coordinating supply of the Product and Revance’s other products from the same CMOs to realize economies of scale; provided that such coordination does not adversely impact the supply of Product to Mylan, its Affiliates and their respective Sublicensees. Regardless of Mylan’s selection of manufacturers of Product, Revance shall supply to Mylan (or Mylan CMO) its

requirements for Biological Active Substance for use in the Product for the Mylan Territory, in accordance with the Supply Agreement.

(d) **Safety Stock.** During the term of the Supply Agreement, Revance will maintain on-hand, solely for sale to Mylan, a [\*] (as determined [\*] depending on [\*] and other relevant factors and based on [\*] under the Supply Agreement) supply of Biological Active Substance. The cost of maintaining such safety stock shall be [\*]. If the available quantity of Biological Active Substance drops below [\*] of the agreed safety stock for reasons [\*], Mylan may request, and the Parties shall hold, a meeting of each Party's CEOs to assess the situation and determine next steps.

(e) **Shelf Life.** Revance shall, in good faith, collaborate with Mylan to extend the shelf life of the Biological Active Substance and Product to [\*], subject to technical feasibility.

(f) **Allocation.** In the event of a shortage of supply of Biological Active Substance or Product, Revance will allocate its available supply of Biological Active Substance or Product, as applicable, between the Parties and supply Mylan with Biological Active Subject or Product [\*].

### 7.3 **Manufacturing Facility.**

(a) **Compliance.** Revance shall ensure that the facility(ies) in which the Biological Active Substance and, to the extent supplied by Revance or a Revance CMO (unless Mylan has elected to obtain supply from such Revance CMO pursuant to an agreement between Mylan and such Revance CMO), the Product is to be manufactured for use or sale in the Mylan Territory (the "**Facility**") is/are in compliance with all Applicable Law, as of the Effective Date and during the term of the Supply Agreement.

(b) **Continued Access to Facility.** Revance shall provide Mylan with written notice of any decision to transfer the lease for the Facility (other than any facility leased by Revance and which was a Facility at a prior point in time, but at which facility Revance is no longer manufacturing Biological Active Substance or Product), or to sell the equipment used to manufacture the Biological Active Substance or the Product (other than with respect to any equipment that is no longer intended for use in the manufacture of the Biological Active Substance or the Product) (the "**Equipment**"), to any party other than its Affiliate (the "**Lease Transfer Notice**"), and Mylan shall, except to the extent otherwise precluded by applicable bankruptcy law in the event of a Bankruptcy Event with respect to Revance, have a right of first offer with respect to assuming or otherwise acquiring the lease for the Facility or acquiring the Equipment. Mylan shall notify Revance, within [\*] days of receipt of the Lease Transfer Notice, whether it desires to assume or otherwise acquire the lease for the Facility or to acquire the Equipment. If Mylan so notifies Revance that it does desire to acquire the lease for the Facility or the Equipment, then Revance shall provide Mylan with appropriate diligence information reasonably requested by Mylan, with respect to such lease, the Equipment, the Facility and its personnel, as soon as possible, subject to confidentiality restrictions then in effect, documented in writing, with its customers or other Third Parties. During the [\*]-day period following Mylan's receipt of a Lease Transfer Notice, (i) Mylan shall have the right to provide Revance with an offer to assume or otherwise acquire the lease for the Facility or acquire the Equipment, which offer Revance will consider in good faith, (ii) Revance will not solicit other offers to assume or otherwise acquire the lease for the Facility or the Equipment, and (iii) if Mylan provides an offer, the Parties will negotiate in good faith to reach agreement for the transfer to Mylan of the lease for the Facility or of the Equipment. If Mylan does not assume or otherwise

acquire the lease for the Facility or acquire the Equipment, Revance shall cause any Third Party acquirer of the Facility or the lease therefor (or substantially all of the Equipment, if appropriate) to continue to supply the Product to Mylan [\*] for the duration of the Term, and in accordance with the terms and conditions of the Supply Agreement. This Section 7.3(b) shall apply with respect to any decision by Revance to transfer the lease for the Facility or the Equipment during the Term.

(c) **Ongoing Maintenance and Capital Expenditures.** [\*] ongoing maintenance costs and capital expenditures associated with the manufacture of the Biological Active Substance for use in the Product for the Mylan Territory, and, [\*], the Product for the Mylan Territory. Without limiting Mylan's rights under Section 7.2 above, in the event that there is a continued failure to supply (as defined in further detail in the Supply Agreement), Mylan shall have the right to manufacture, or have manufactured (through an Affiliate or Third Party) the Product (but not the Biological Active Substance) for the Mylan Territory, in which case (i) Revance will conduct a transfer, to Mylan or such Third Party, of all Licensed Know-How that is necessary or reasonably useful in the manufacture of the Product in accordance with Section 7.4 (and grant the licenses and rights set forth therein), at Revance's expense, and (ii) after such transfer, [\*] ongoing maintenance costs and capital expenditures associated with the manufacture of the Product for the Mylan Territory. Regardless of Mylan's election to manufacture (or have manufactured) Product, Revance shall supply to Mylan its requirements for Biological Active Substance for use in the Product for the Mylan Territory, in accordance with the Supply Agreement.

(d) **Continuous Improvements Program.** The Parties shall collaborate to develop a continuous improvements program to reduce Manufacturing Costs. Such program will be reviewed and approved by the JSC (and will include an allocation of cost sharing with respect to any such improvements). Revance will use Commercially Reasonable Efforts to implement such program and reduce Manufacturing Costs during the Term.

7.4 **Transfer of Manufacturing Know-How.** At Mylan's request and in accordance with the Supply Agreement, in order to qualify a manufacturing site for manufacture of Product, Revance shall disclose (and provide copies or provide access to make copies, as applicable) to either Mylan or a CMO selected by Mylan, all Licensed Know-How (but excluding in all cases the Cell Line) and Licensed Material that is necessary or reasonably useful in the manufacturing (including quality assurance and control testing, filling, labeling, packaging, finishing, storage and shipping, as applicable) of the Product. In addition, Revance shall provide the appropriate authorizations to all relevant Regulatory Authority(ies) allowing Mylan (or its CMO) the right to reference all Drug Master Files and Product-Related Data provided to a Regulatory Authority by or on behalf of Revance or its permitted contractors to support any necessary changes to Regulatory Filings or the Marketing Authorization for the Product to permit manufacture of the Product by Mylan or its CMO for the Mylan Territory, and grant Mylan or its CMO any necessary licenses under the Licensed Technology Rights to manufacture the Product. In connection with the foregoing provisions, Revance shall make available to Mylan, [\*], such advice of its technical personnel as may reasonably be requested by Mylan in connection with such transfer, understanding and implementation of such manufacturing-related Licensed Know-How.

#### 7.5 **Costs of Transfer.**

(a) If, at the time of Mylan's election to use a Mylan CMO, [\*] and [\*] to manufacture the Product for the Mylan Territory (based on Mylan's then-current forecasts under the Supply Agreement)

or [\*], then [\*] the costs of qualifying an additional Mylan CMO; provided that Revance shall assist Mylan, at Mylan's request, in qualifying such Mylan CMO. [\*] such assistance would be provided by Revance [\*]. For [\*] qualifying such CMO, Mylan would [\*].

(b) If, at the time of Mylan's election to use a Mylan CMO, (1) [\*] to manufacture the Product for the Mylan Territory (based on Mylan's then-current forecasts under the Supply Agreement) and [\*] or (2) [\*], or [\*] Product to Mylan in accordance with this Agreement and the Supply Agreement, then Revance will assist Mylan, at Mylan's request, in qualifying such Mylan CMO and [\*] the costs of qualifying such Mylan CMO.

7.6 **Clinical Supply.** Without limiting the foregoing, Revance shall be and remain responsible for manufacturing any Product necessary to support the Development activities under the Development Plan, [\*], in accordance with this Agreement, the Supply Agreement and all Applicable Laws, including cGMPs.

## ARTICLE 8

### PAYMENTS

8.1 **Initial Payment.** In partial consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance the initial payment as set forth in paragraph 1 of the Financial Exhibit.

8.2 **FDA Advisory Milestone Payment.** If Mylan provides a Continuation Notice that it will continue with Development and commercialization of the Product for the Mylan Territory under this Agreement pursuant to Section 5.2(c), Revance shall issue to Mylan an invoice for, and Mylan shall pay, the FDA Advisory Milestone Payment (plus Mylan's share of any Excess Revance Costs) as set forth in paragraph 2 of the Financial Exhibit.

8.3 **Contingent Development Milestone Payments.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Revance shall issue to Mylan an invoice for, and Mylan shall pay to Revance, the contingent milestone payments for the achievement of certain development and regulatory milestone events as set forth in paragraph 3 of the Financial Exhibit.

8.4 **Contingent Commercial Milestone Payments.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Revance shall issue to Mylan an invoice for, and Mylan shall pay to Revance, the contingent milestone payments for the achievement of certain commercial milestone events as set forth in paragraph 4 of the Financial Exhibit.

8.5 **Royalties.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance royalties during the Term as set forth in paragraph 5 of the Financial Exhibit and Section 14.6(b). In addition, Revance shall pay to Mylan royalties as set forth in Section 14.6(c) and Section 14.7.



8.6 **Development Costs.** The Parties shall share Development Costs in accordance with Article 5 above and paragraph 6 of the Financial Exhibit.

8.7 **Right to Offset.** Each Party may offset against any undisputed amounts owed to the other Party hereunder, any undisputed amounts owed but not yet paid by the other Party under this Agreement, subject to such limits as may be expressly provided in this Agreement.

## ARTICLE 9

### PAYMENT TERMS

9.1 **Payment Method.** All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. Except as otherwise set forth herein, invoices issued in accordance with this Agreement shall be paid within [\*] days of receipt of such invoice.

9.2 **Currency Conversion.** Unless otherwise expressly stated in this Agreement, all amounts specified in this Agreement are in United States Dollars, and all payments by one Party to the other Party under this Agreement shall be paid in United States Dollars. In the case of sales outside the United States, payments received by a Party will be expressed in the U.S. Dollar equivalent calculated on a quarterly basis in the currency of the country of sale and converted to their U.S. Dollar equivalent using the average of the daily closing prices for each month in such quarter for such currency reported on Bloomberg.

### 9.3 **Taxes.**

(a) **Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the collaborative efforts of the Parties under this Agreement.

(b) **Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts in accordance with Applicable Law to reduce value added tax or similar payments (“**VAT**”), tax withholding and similar obligations on royalties, milestone payments, and other payments made under this Agreement.

(c) **VAT.** In the event that any VAT is owing in any jurisdiction in respect of any payment made by one Party to the other Party under this Agreement, the Party making such payment (the “**Payer**”) shall pay such VAT, and (i) if such VAT is owing [\*], then the payment in respect of which such VAT is owing shall be made without deduction for or on account of such increase in VAT to ensure that the other Party receives a sum equal to the sum which it would have received had such increased VAT not been due or (ii) otherwise, such payment shall be made after deduction of such VAT. Any increase in payments to a Party under this Section 9.3(c) shall reflect only the incremental increase in VAT directly resulting from clause (i) above. In the event that any VAT is owing in any jurisdiction in respect of any such payment, the Payer will provide to the other Party tax invoices showing the correct amount of VAT in respect of such payments hereunder.

(d) **Withholdings.** Any and all withholding or similar taxes imposed or levied on account of the payment of amounts under this Agreement, which are required to be withheld, shall be

deducted by the payer prior to remittance and shall be paid to the proper taxing authority. Proof of payment shall be secured, if available, and sent to the Payee as evidence of such payment in such form as required by the tax authorities having jurisdiction over the payer. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

#### 9.4 **Audit Rights.**

(a) **By Mylan.** Revance will maintain complete and accurate records in sufficient detail to permit Mylan to confirm Revance's compliance with the terms of this Agreement and the accuracy of Revance's calculations under this Agreement, including with respect to Development Costs, Manufacturing Costs, and Reverted Country Product Revenues. Such records relating to this Agreement and Revance's facilities used in the development and manufacture of the Product shall be available for audit and inspection during regular business hours for a period of [\*] years from the end of the calendar quarter to which they pertain, and not more often than once each calendar year, unless the audit reveals non-compliance or overpayment. Such audits and inspections may be conducted by Mylan or its Third Party designee, which is reasonably acceptable to Revance; *provided* that Revance may require that any such designee agrees to be bound by a reasonable confidentiality agreement, and *provided further* that any such financial audit may be conducted only by a certified public accounting firm mutually agreed upon by Mylan and Revance, such agreement not to be unreasonably withheld. Mylan shall provide Revance with [\*] calendar days' prior written notice of any such audit, and the duration of any such audit shall be limited to a reasonable period of time. Mylan or its designee may examine Revance's records and facilities relating to this Agreement for the sole purpose of verifying Revance's compliance with the terms of this Agreement and the accuracy of the aforesaid calculations. With regard to such calculations, the accountants shall disclose to Mylan, with a copy to Revance, only whether the amounts reported or invoiced by Revance are correct or incorrect, and the amount of discrepancy, if any. Once examined, such books and records will no longer be subject to further examination by Mylan under this Section 9.4(a). Any amounts shown to have been overcharged shall be refunded by Revance to Mylan within [\*] calendar days from the accountant's report. Mylan shall bear the full cost of such audit unless such audit discloses an overcharge of more than [\*] of the amount actually owed during the applicable calendar quarter, in which case Revance shall reimburse Mylan for its reasonable Third Party out-of-pocket costs incurred for such audit. Revance shall cause any of its subcontractors performing activities related to this Agreement to comply with the recordkeeping requirements of this Section 9.4(a) and to permit Mylan to audit such records as described above.

(b) **By Revance.** Mylan will maintain complete and accurate records in sufficient detail to permit Revance to confirm Mylan's compliance with the terms of this Agreement and the accuracy of Mylan's calculations under this Agreement, including with respect to Net Sales, royalties, and Development Costs. Such records relating to this Agreement shall be available for audit and inspection during regular business hours for a period of [\*] years from the end of the calendar quarter to which they pertain, and not more often than once each calendar year, unless the audit reveals non-compliance or underpayment. Such audits and inspections may be conducted by Revance's Third Party designee, which is reasonably acceptable to Mylan; *provided* that Mylan may require that any such designee agrees to be bound by a reasonable confidentiality agreement, and *provided further* that any such financial audit may be conducted only by a certified public accounting firm mutually agreed upon by Mylan and Revance, such agreement not to be unreasonably withheld. Revance shall provide Mylan with [\*] calendar days'

prior written notice of any such audit, and the duration of any such audit shall be limited to a reasonable period of time. Revance or its designee may examine Mylan's records relating to this Agreement for the sole purpose of verifying Mylan's compliance with the terms of this Agreement and the accuracy of the aforesaid calculations. With regard to such calculations, the accountants shall disclose to Revance, with a copy to Mylan, only whether the Net Sales, royalties, Development Costs reported and underlying amounts owed hereunder are correct or incorrect, and the amount of discrepancy, if any. Once examined, such books and records will no longer be subject to further examination by Revance under this Section 9.4(b). Any amounts shown to have been underpaid shall be paid by Mylan to Revance within [\*] calendar days from the accountant's report. Revance shall bear the full cost of such audit unless such audit discloses an underpayment of more than [\*] of the amount actually owed during the applicable calendar quarter, in which case Mylan shall reimburse Revance for its reasonable Third Party out-of-pocket costs incurred for such audit. Mylan shall cause any of its subcontractors performing activities related to this Agreement to comply with the recordkeeping requirements of this Section 9.4(b) and to permit Revance to audit such records as described above.

## ARTICLE 10

### STRATEGY; DEFENSIVE ACTIONS; INTELLECTUAL PROPERTY

#### 10.1 **Litigation Strategy and Management.**

(a) Subject to the terms and conditions of this Article 10, Mylan shall have the primary right to control all intellectual property matters and strategic matters for the Product in the Mylan Territory, including the right, but not the obligation, to conduct applicable intellectual property searches and freedom-to-operate analyses, and control and initiate strategic decisions relating to potential intellectual property litigation, and Post-Grant Review Proceedings, using counsel of its choice. Without limiting the foregoing, Mylan shall be responsible for devising, and have primary control over the implementation of, any Legal Clearance Activities in the Mylan Territory. Mylan shall submit an initial, non-binding preliminary Legal Clearance Activities plan to the JSC not later than [\*]. All costs actually incurred by or on behalf of Mylan or its Affiliates on or after the Signing Date, including all FTE costs measured at the FTE Rate and out-of-pocket expenses, in connection with legal work and advice relating to intellectual property matters and strategic matters for the Product in the Mylan Territory, including: (a) researching and analyzing freedom to operate; (b) citizen's petitions proceedings; and (c) creation of a litigation strategy for the Product ("**Legal Strategy Costs**"), shall be [\*]. Nothing in this Section 10.1 shall in any way limit or be construed as impairing Revance's sole rights to control all intellectual property matters and strategic matters for products comprising botulinum neurotoxin which are other than the Product, anywhere in the world.

(b) **Consultation.** Without limiting Mylan's rights under Section 10.1(a), the Parties shall, through the JSC, regularly discuss and consult with respect to Legal Clearance Activities plans and strategy. In addition, the Parties shall have Legal Clearance Activities review meetings, at a frequency determined by the JSC. Once the BPCI Act exchange process for the Product commences, Revance shall participate as necessary to sustain jurisdiction and shall provide information regarding the Product (including the Biological Active Substance) and its manufacture, as well as the Licensed Intellectual Property, in each case as reasonably requested by Mylan in connection with any Legal Clearance Activities.

## 10.2 **Defensive Actions.**

(a) **Notice.** Each Party shall promptly notify the other Party if any Third Party claims or asserts that the Biological Active Substance or Product manufactured, used or sold by or under the authority of either Party or its Affiliates infringes a Patent(s) of a Third Party or misappropriates proprietary Know-How of a Third Party, or otherwise threatens or initiates any litigation or proceeding in any court or Governmental Authority that could delay Marketing Authorization of the Product, or result in withdrawal or suspension of such Marketing Authorization or the Product from the market, including litigation arising from or related to any Legal Clearance Activities or patent infringement litigation (any such litigation or proceeding, a “**Defensive Action**”).

(b) **Control.** Except as set forth below in Section 10.2(d), Mylan shall have the first right to defend and control any such Defensive Action related to patent infringement that is initiated or pursued in the Mylan Territory, or, pursuant to the provisions of the BPCI Act, to bring and control any declaratory judgment action with respect thereto, using counsel of its own choice, as well as to negotiate and settle any Defensive Action. If Mylan elects not to defend and control any such Defensive Action related to patent infringement that is initiated or pursued in the Mylan Territory, or to bring and control any declaratory judgment action with respect thereto, as well as to negotiate and settle any Defensive Action, then it shall so notify Revance in writing, and Revance may, in its sole judgment, and at its own expense, take steps to defend and control any such Defensive Action related to patent infringement that is initiated or pursued in the Mylan Territory, or to bring and control any declaratory judgment action with respect thereto, using counsel of its own choice, as well as to negotiate and settle any Defensive Action. Neither Party shall enter into any settlement of any claim described in this Section 10.2 that admits to the invalidity or unenforceability of any Patent Right, incurs any financial liability on the part of the other Party or requires an admission of liability, wrongdoing or fault on the part of the other Party without the other Party’s prior written consent. Each Party shall provide the other Party with reasonable assistance in any such Defensive Action or declaratory judgment action in the Mylan Territory, at such Party’s request and expense, including joining as a party plaintiff as necessary or useful and entering into a common interest or joint defense agreement, wherein the Parties agree to their shared, mutual interest in the outcome of such Defensive Action or declaratory judgment action. The Party controlling a Defensive Action agrees to keep the other Party reasonably and periodically informed of all material developments in connection with any such Defensive Action in the Mylan Territory (including the filing of any related declaratory judgment action that the Product does not infringe the applicable Patent(s) of the NDA Holder), and Revance agrees to keep Mylan informed of any similar actions or proceedings in the Revance Territory.

(c) **Costs of Defensive Actions in the Mylan Territory.** In the event that any Defensive Action related to patent infringement is initiated or pursued in the Mylan Territory by either Party, or a Party pursues a declaratory judgment proceeding in the Mylan Territory with respect thereto, except as expressly set forth herein, [\*] any and all legal defense costs, attorneys’ fees and liability (“**Legal Expenses**”) [\*] in connection with such Defensive Action or declaratory judgment action or proceeding. For clarity, the foregoing shall [\*].

(d) [\*]. Notwithstanding the foregoing, in the event that the Innovator brings a Defensive Action claiming that [\*], [\*] shall be responsible for defending such Defensive Action. [\*] any and all legal defense costs and attorneys’ fees incurred in connection with such Defensive Action [\*]. [\*] shall provide [\*] with reasonable assistance in any such Defensive Action described in this Section

10.2(d), including joining as a party plaintiff as necessary or useful and entering into a common interest or joint defense agreement, wherein the Parties agree to their shared, mutual interest in the outcome of such Defensive Action or declaratory judgment action. [\*] agrees to keep [\*] reasonably and periodically informed of all material developments in connection with any such Defensive Action. [\*] shall not enter into any settlement of any claim described in this Section 10.2(d) that results in any financial liability on the part of [\*] or requires an admission of liability, wrongdoing or fault on the part of [\*] without [\*] prior written consent. If damages are assessed (or agreed upon through settlement) with respect to any claim described in this Section 10.2(d), then (x) [\*] shall be responsible for [\*] of any such damages that are attributable to sales of the Product in the Mylan Territory prior to such damages being awarded; provided, however that such damages, as well as its share of legal defense costs and attorneys' fees are [\*], and (y) [\*] shall be responsible for [\*] of such damages. Additionally, in the event the Innovator is entitled to (or any settlement includes) royalty payments based upon future sales of Product in the Mylan Territory, [\*] will be responsible for such payments, but will be entitled to [\*]; *provided* that in no event shall [\*].

10.3 **Ownership of Inventions.** Subject to the licenses set forth in Article 2 and the rights set forth in this Article 10, Revance shall retain ownership of the Licensed Technology Rights other than the Collaboration Data. As between the Parties all right, title and interest to inventions, Know-How and other intellectual property (together with all intellectual property rights therein) conceived or created or first reduced to practice in connection with the exercise of rights or performance of obligations under this Agreement (“**Inventions**”) (i) by or under the authority of Mylan or its Affiliates or Sublicensees, independently of Revance and its Affiliates, shall be owned by Mylan (“**Mylan Inventions**”); (ii) by or under the authority of Revance or its Affiliates or Sublicensees, independently of Mylan and its Affiliates, shall be owned by Revance; and (iii) by personnel of Mylan or its Affiliates and Revance or its Affiliates shall be jointly owned by Mylan and Revance. Any patent application claiming an Invention that is jointly owned by the Parties, which is filed by a Party or its Affiliate after the Effective Date, together with any resulting patent, may be referred to herein as a “**Joint Patent**”. Revance’s interest in any Inventions that are necessary or useful to the Exploitation of the Cell Line, Biological Active Substance, Product or a component of the Product in the Mylan Territory, and all intellectual property rights therein, shall be automatically included in the Licensed Technology Rights. Mylan’s interest in any Inventions that are necessary or useful to the Exploitation of the Product in the Revance Territory, and all intellectual property rights therein, shall be automatically included in the Mylan Technology Rights. Except as expressly provided otherwise in this Agreement, neither Party shall have any obligation to obtain any approval of the other Party for, nor pay the other Party any share of the proceeds from or otherwise account to the other Party for, the practice, enforcement, licensing, assignment or other exploitation of such jointly owned Inventions or Joint Patent or other intellectual property rights therein, and each Party hereby waives any right it may have under the laws of any country to require such approval, sharing or accounting. Notwithstanding anything to the contrary in this Agreement, but subject to the rights and licenses granted under this Agreement, as between the Parties, each Party retains ownership of its inventions, Know-How and other intellectual property (together with all intellectual property rights therein) conceived or created or first reduced to practice before the Effective Date or outside of the Initial Development Plan or the Development Plan.

10.4 **Prosecution and Maintenance of Patents and Joint Patents.** Revance shall have the right and responsibility, in its sole discretion, to prepare, file, prosecute (including the handling of Post Grant Review Proceedings, supplemental examination, and similar proceedings with respect to the

Licensed Intellectual Property Rights and Joint Patents) and maintain patent protection with respect to the Licensed Intellectual Property Rights in the Mylan Territory or the Joint Patents, taking into account comments from Mylan with respect thereto. Revance shall keep Mylan reasonably informed with respect to the status of the Licensed Patents in the Mylan Territory and the Joint Patents, including by providing Mylan with copies of all material documentation or correspondence concerning the Licensed Patents in the Mylan Territory and the Joint Patents. Revance shall solicit Mylan's comments prior to filing any new Patent Right that would be a Licensed Intellectual Property Right in the Mylan Territory or any Joint Patent and shall consider Mylan's reasonable comments with respect thereto in good faith. If Revance decides to abandon, or otherwise fails to prosecute or maintain, any Licensed Patent in the Mylan Territory or any Joint Patent, Revance shall provide Mylan with written notice of such decision at least [\*] days prior to any applicable filing deadline, and of any such failure promptly after it occurs. In such case, Mylan shall have the right, but not the obligation, to prepare, file, prosecute and maintain patent protection with respect to such Licensed Patent or Joint Patent, as applicable, in such country at its own expense.

10.5 **Enforcement of Patents and Joint Patents.** Each Party shall promptly report to the other Party during the Term after the Effective Date any known or suspected infringement or unauthorized use of any Licensed Patent in the Mylan Territory or Joint Patent (each, a "**Patent Infringement Notice**"), as the case may be, of which such Party becomes aware, and, upon request, shall provide the other Party with all evidence within its possession or control supporting such known or suspected infringement or unauthorized use. Mylan will have the first right but not the obligation to enforce (a) the Licensed Patents against any Third Party infringement based on the manufacture, use, sale or importation of the Product in or for the Mylan Territory or (b) the Joint Patents against any Third Party infringement. If Mylan elects to pursue such an enforcement action, Mylan shall be solely responsible for the expenses associated with such action. In the event that Mylan does not undertake such an enforcement action within [\*] days of the Patent Infringement Notice, Revance shall be permitted to do so and, if it elects to undertake such an enforcement action, Revance shall be solely responsible for the expenses associated with such action. If a Party is authorized to bring an enforcement action under this Section 10.5, but the Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall, at the enforcing Party's request and expense, join as a party-plaintiff. Any damages, awards, settlement payments or other recoveries resulting from an enforcement action brought by a Party pursuant to this Section 10.5 with respect to infringement of the Licensed Patents in the Mylan Territory based on the Exploitation of the Product, or with respect to infringement of the Joint Patents shall first be used to cover the Parties' costs with respect thereto and any remainder shall be shared as follows: [\*].

## ARTICLE 11

### REPRESENTATIONS AND WARRANTIES

11.1 **Due Organization, Valid Existence and Due Authorization.** As of the Signing Date and as of the Effective Date, each Party hereto represents and warrants to the other Party as follows: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement, court order, consent decree or other arrangement, whether written or oral, by which it is bound; and (d) this Agreement is its legal, valid and binding obligation, enforceable against such Party in accordance with the terms and

conditions hereof, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by the principles governing the availability of equitable remedies.

11.2 **Representations, Warranties and Covenants of Revance.** In addition to the representations and warranties of Revance under Section 11.1 above, as of the Signing Date and as of the Effective Date, Revance hereby further represents, warrants and covenants to Mylan that:

(a) It owns the entire right, title and interest in, or otherwise has the right to grant the licenses and rights granted to Mylan herein under the Licensed Technology Rights, and Revance and its Affiliates have not, and shall not, grant any rights that conflict with such licenses and rights or that would otherwise prevent Mylan from exercising its rights or performing its obligations hereunder. Without limiting the foregoing, Revance represents and warrants that it owns all right, title and interest in and to the Licensed Patents;

(b) There are no Patent Rights or Know-How owned or Controlled by Revance or its Affiliates as of the Signing Date or the Effective Date that are necessary for, or used by Revance or its Affiliates prior to the Signing Date or the Effective Date in, the manufacture, development or commercialization of the Biological Active Substance or the Product, other than the Licensed Patents licensed to Mylan hereunder;

(c) Revance has sufficient rights with respect to the Cell Line to conduct its manufacturing obligations with respect to the Biological Active Substance and the Product in accordance with this Agreement and the Supply Agreement using the Cell Line. The Cell Line Agreement is, and shall remain during the Term, in full force and effect, except to the extent that any termination has no adverse effect on Revance's rights to so manufacture and supply the Biological Active Substance and the Product, such as by virtue of Revance buying out its rights thereunder. Revance shall not make any amendments to the Cell Line Agreement that would adversely affect the rights of Mylan under this Agreement, or terminate the Cell Line Agreement without Mylan's prior written consent, except to the extent that any termination has no adverse effect on Revance's rights to so manufacture and supply the Biological Active Substance and the Product, by virtue of Revance buying out its rights thereunder;

(d) The contracts listed on Exhibit 11.2(d) are the only contracts or agreements between Revance (or its Affiliate) and any other Third Parties related to the Cell Line, Biological Active Substance, Product, or the development, manufacture or commercialization thereof, other than with respect to inactive materials used in such manufacture;

(e) Except as required under contracts listed on Exhibit 11.2(d), Revance is not subject to any Third Party payment obligations associated with its use of the Cell Line in accordance with this Agreement or otherwise with respect to the development, manufacture or commercialization of the Product in accordance with this Agreement;

(f) The Licensed Intellectual Property Rights are subsisting, valid and enforceable, and are not subject to any pending or threatened opposition, interference or litigation proceedings;

(g) The Licensed Technology Rights are free and clear of all liens, claims, security interests or other encumbrances of any kind;

(h) There are no claims, judgments or settlements against or owed by Revance or its Affiliates, or pending claims or litigation, relating to the Biological Active Substance, Product, components of the Product, or Licensed Technology Rights;

(i) To Revance's knowledge, the development, manufacture, processing or commercialization of any Cell Line, Product or component of the Product, and the use of the Licensed Technology Rights, pursuant to the provisions of this Agreement and as contemplated herein has not, does not and will not misappropriate the Know-How of any Third Party [\*], or, to the knowledge of Revance, infringe the Patent Rights, of any Third Party;

(j) Revance has not, nor to its knowledge, has any Third Party acting under authority of Revance, made an untrue statement of a material fact to any Regulatory Authority with respect to the Product, or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Product. Revance has, and to its knowledge such Third Parties have, complied and will comply with all regulatory requirements with respect to the Biological Active Substance and Product. All Product-Related Data within the Licensed Know-How have been generated in compliance with all Applicable Law, including, as applicable, cGMP, good clinical practices, ICH guidelines, and all Regulatory Filings within the Licensed Know-How submitted to any Regulatory Authority are true and correct in all material respects;

(k) Revance's manufacturing facilities (and those of its subcontractors) for the Biological Active Substance and the Product are compliant with Applicable Law, including cGMP. Revance and its subcontractors hold all permits, licenses and authorizations required under Applicable Law to use such facilities to manufacture the Product for human use in the Mylan Territory, all of which are current and in good standing; further, Revance holds, and will maintain during the Term, all certifications, permits, licenses and authorizations required under Applicable Law to access, transfer, manufacture, store and use the Biological Active Substance in accordance with this Agreement, and is, and will remain during the Term, in compliance with all such certifications, permits and authorizations;

(l) Neither Revance nor any of its employees or permitted subcontractors performing or involved with the development or commercialization of the Product or its performance under this Agreement have been "debarred" or excluded from reimbursement by the FDA or any other Regulatory Authority, nor have debarment or exclusion proceedings against Revance or any of its employees or permitted subcontractors been commenced; and

(m) (i) No Clinical Trials of the Product have been conducted, and (ii) all non-clinical studies of the Product that have been conducted by or on behalf of Revance that have been submitted to any Regulatory Authority in connection with the Product, have been conducted in compliance in all material respects with Applicable Law, including good clinical practices and good laboratory practices, as applicable.

### 11.3 **Anti-Corruption Laws.**

(a) Revance understands that Mylan is required to abide by the United States Foreign Corrupt Practices Act ("FCPA"), the United Kingdom Bribery Act ("UKBA") and any other applicable anti-corruption laws (collectively, the "**Anti-Corruption Laws**"). Each Party represents and warrants that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly



or indirectly, of any money or other thing of value to anyone as an inducement or reward for favorable action or forbearance from action or the exercise of influence (a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other Person or entity in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

(b) Each Party understands that the other Party may immediately suspend payment, in its sole discretion and without notice, if the actions or inactions of such Party become subject to an investigation of potential violations of the Anti-Corruption Laws. Moreover, each Party understands that if the other Party determines that such Party failed to comply with the provisions of any Applicable Law, including the Anti-Corruption Laws, the other Party may immediately terminate this Agreement, and any payments due hereunder, in its sole discretion and without notice (*provided*, that any such termination shall be limited to the country or countries in which the actions or inactions constitute a violation of Applicable Law).

(c) Each Party warrants that all Persons acting on its behalf will comply with all Applicable Laws in connection with all work under this Agreement, including the Anti-Corruption Laws if any, prevailing in the country(ies) in which such Party has its principal places of business, and with respect to Persons acting on behalf of such Party, in which such Person performs work on behalf of such Party.

(d) Each Party further warrants and represents that should it learn or have reason to suspect any breach of the representations, warranties or covenants in this Section 11.3, it will immediately notify the other Party.

#### 11.4 Trade Control Laws.

(a) Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including the U.S. Export Administration Regulations (Title 15 of the U.S. Code of Federal Regulations Part 730 et seq.) and the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign Assets Control (Title 31 of the U.S. Code of Federal Regulations Part 500 et seq.) (collectively, "**Trade Control Laws**").

(b) Each Party acknowledges and confirms that Trade Control Laws apply to its activities, its employees and Affiliates under this Agreement.

(c) No Product will be directly or indirectly shipped by a Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses, even for transfer to non-sanctioned countries, and only after the express written consent of both Parties.

(d) Neither Party shall be required by the terms of this Agreement to be directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws if performed by such Party. It shall be in the sole discretion of each Party

to refrain from being directly or indirectly involved in the provision of goods, services or technical data that may be prohibited by applicable Trade Control Laws.

(e) Each Party hereby represents and warrants that it is not included on any of the restricted party lists maintained by the U.S. Government, including the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control; the Denied Persons List, Unverified List or Entity List maintained by the U.S. Commerce Department's Bureau of Industry and Security; or the List of Statutorily Debarred Parties maintained by the U.S. State Department's Directorate of Defense Trade Controls.

(f) Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent Product from being exported or re-exported to any country, entity or individual subject to U.S. trade sanctions, unless prior approval of the other Party, and relevant permission or license from the U.S. government has been obtained.

(g) Each Party will keep accurate and consistent records of all transactions under this Agreement covered by the Trade Control Laws for a minimum of five (5) years from the date of export or re-export; the date of expiration of any applicable license; or, other approval or reliance on any application of license exception or exemption.

11.5 **Disclaimer.** EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 11 OR ELSEWHERE IN THIS AGREEMENT OR ANY ANCILLARY AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED OR STATUTORY, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, IMPLIED OR STATUTORY, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST NON-INFRINGEMENT OR THE LIKE, OR ARISING FROM COURSE OF PERFORMANCE.

## ARTICLE 12

### CONFIDENTIALITY

12.1 **"Confidential Information"** means the terms and provisions of this Agreement (each of which shall be the Confidential Information of both Parties) and all other information and data, including all notes, books, papers, diagrams, documents, reports, e-mail, memoranda, visual observations, oral communications and all other data or information in whatever form, that one Party or any of its Affiliates or representatives (the **"Disclosing Party"**) has supplied or otherwise made available to the other Party or its Affiliates or representatives (the **"Receiving Party"**) hereunder, including those made prior to the Effective Date of this Agreement, subject in all cases to Section 12.3(a). This Article 12 shall supersede that certain confidentiality agreement between the Parties dated [\*] (the **"Prior CDA"**), and all Confidential Information disclosed pursuant to the Prior CDA shall be deemed to have been disclosed hereunder.

12.2 **Obligations.** The Receiving Party shall protect all Confidential Information of the Disclosing Party against unauthorized use and disclosure to Third Parties with the same degree of care

as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The Receiving Party shall be permitted to disclose to Third Parties and to use the Confidential Information of the Disclosing Party solely as reasonably necessary to exercise its rights and fulfill its obligations under this Agreement (including any surviving rights), including (a) in prosecuting or defending litigation, (b) complying with Applicable Law, or (c) otherwise submitting information to tax or other Governmental Authorities. The Receiving Party shall not disclose the Confidential Information of the Disclosing Party to any Third Party other than to its Affiliates, and its and their respective directors, officers, employees, subcontractors, sublicensees or prospective sublicensees (solely to the extent necessary for such sublicensees to perform their obligations pursuant to its sublicense under this Agreement), consultants, attorneys, accountants, banks and investors (collectively, “**Recipients**”) who have a need to know such information for purposes related to this Agreement and who are bound by obligations of confidentiality at least as protective of such Confidential Information as those set forth in this Agreement.

### 12.3 **Exceptions.**

(a) **Restriction Limitations.** The restrictions related to use and disclosure under this Article 12 shall not apply to any information disclosed by a Disclosing Party to the extent the Receiving Party can demonstrate by competent evidence that such information:

(i) is (at the time of disclosure by the Disclosing Party) or becomes (after the time of such disclosure by the Disclosing Party) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party, or any Recipient to whom the Receiving Party disclosed such information, of its confidentiality obligations to the Receiving Party;

(ii) was known to, or was otherwise in the possession of, the Receiving Party prior to the time of disclosure by the Disclosing Party;

(iii) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is not, to the actual knowledge of the Receiving Party, prohibited from disclosing it without breaching any confidentiality obligation to the Disclosing Party; or

(iv) is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without use of or access to the Confidential Information.

(b) **Disclosure Required by Law.** The restrictions set forth in Section 12.2 shall not apply to the extent that the Receiving Party is required to disclose any Confidential Information under law or by an order of a Governmental Authority; *provided* that the Receiving Party: (i) provides the Disclosing Party with prompt written notice of such disclosure requirement if legally permitted, (ii) affords the Disclosing Party an opportunity, and cooperates with the Disclosing Party’s efforts, to oppose or limit, or secure confidential treatment for such required disclosure (at the Disclosing Party’s expense), and (iii) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (ii), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party’s legal counsel.

12.4 **Publication of Product Information.** After the Effective Date, Revance shall not publish, or publicly present, or submit for written or oral publication, any manuscript or information regarding the Products, including the Collaboration Data, without Mylan's prior consent; *provided* that the foregoing shall not prevent Revance from publishing information regarding the Products resulting from its third party licensee's development and commercialization of the Product outside of the Mylan Territory.

12.5 **Public Announcements.** The Parties have agreed to make a joint public announcement of the execution of this Agreement the text of which is attached as Exhibit 12.5, which will be issued at a time to be mutually agreed by the Parties. Except for such joint press release or as may be expressly permitted under Section 12.2 or required by Applicable Law (including any SEC filing requirements), neither Party will make any public announcement, or any other written or oral disclosure, regarding this Agreement or the terms hereof, the collaboration between the Parties hereunder, the Product or any Development, manufacturing or commercialization activities conducted under this Agreement (the "**Public Announcement Matters**") without the prior written approval of the other Party, which approval shall not be conditioned, delayed, refused or withheld unreasonably; *provided however*, that neither Party shall be prevented from complying with any duty of disclosure that it may have pursuant to Applicable Law or the rules of any recognized stock exchange so long as the Disclosing Party provides the other Party at least five (5) Business Days prior written notice of such disclosure to the extent practicable and only discloses information to the extent required by applicable Laws or the rules of any recognized stock exchange. Once any statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party provided such information remains accurate as of such time. Notwithstanding anything herein to the contrary, either Party may inform its customers, suppliers and business contacts of the licensing of the Products hereunder in the ordinary course of business. Notwithstanding the restrictions contained in this Article 12, each Party will have the right to disclose this Agreement or the terms of this Agreement to any bona fide potential or actual investor, acquiror or other financial partner, in each case as reasonably necessary in connection with the consideration of the applicable transaction, provided that prior to any such disclosure, each disclosee is bound by obligations of confidentiality and non-use (which non-use obligations shall limit the use of such information to such Person's consideration of the applicable transaction or for use in connection with its activities as an investor, acquiror or financial partner) and which obligations of confidentiality and non-use shall otherwise be at least equivalent in scope as those set forth in this Article 12 (except for the term of such obligations, which shall be for a commercially reasonable period).

12.6 **Use of Product Information.** Revance will not knowingly use or permit the use of any Confidential Information relating solely to the Product (and not relating to Revance Existing Products) for purposes of promoting the Existing Revance Products or any other Competing Product.

12.7 **Right to Injunctive Relief.** Each Party agrees that breaches of this Article 12 may cause irreparable harm to the other Party and shall entitle such other Party, in addition to any other remedies available to it (subject to the terms of this Agreement), to the right to seek injunctive relief enjoining such action.

12.8 **Ongoing Obligation for Confidentiality.** The Parties' obligations of confidentiality, non-use and non-disclosure under this Article 12 shall survive any termination of this Agreement for [\*] years.

## ARTICLE 13

### INDEMNIFICATION; INSURANCE

#### 13.1 Indemnification.

(a) **Indemnification by Revance.** Subject to Section 13.1(d) below, Revance hereby agrees, at its sole cost and expense, to defend, hold harmless and indemnify, to the extent permitted by Applicable Law (collectively, “**Indemnify**”), Mylan and its Affiliates and their respective agents, directors, officers and employees and the respective successors and assigns of any of the foregoing (the “**Mylan Indemnitees**”) from and against any and all liabilities, damages, penalties, fines, costs and expenses (including, reasonable attorneys’ fees and other expenses of litigation) (collectively, “**Liabilities**”) resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a “**Third-Party Claim**”) against any Mylan Indemnatee and arising from or occurring as a result of: (i) the development, manufacture, processing, storage, handling, use, marketing, distribution, offer for sale, sale, promotion, importation or other commercialization of the Biological Active Substance, Cell Line, or Product by or on behalf of Revance, its Affiliates or licensees (other than Mylan); (ii) any material breach of any of Revance’s obligations, representations, warranties or covenants under this Agreement or any Ancillary Agreement; or (iii) the gross negligence or willful misconduct of a Revance Indemnatee under this Agreement or any Ancillary Agreement. Revance’s obligation to Indemnify the Mylan Indemnitees pursuant to this Section 13.1(a) shall not apply to the extent that any such Liabilities result from clause (i), (ii), or (iii) in Section 13.1(b) below.

(b) **Indemnification by Mylan.** Subject to Section 13.1(d) below, Mylan hereby agrees to Indemnify Revance and its Affiliates and their respective agents, directors, officers and employees and the respective successors and assigns of any of the foregoing (the “**Revance Indemnitees**”) from and against any and all Liabilities resulting from Third-Party Claims against any Revance Indemnatee arising from or occurring as a result of: (i) the development, manufacture, processing, storage, handling, use, marketing, distribution, offer for sale, sale, promotion, importation or other commercialization of the Biological Active Substance, Cell Line, or Product by or on behalf of Mylan, its Affiliates or Sublicensees; (ii) any material breach of any of Mylan’s obligations, representations, warranties or covenants under this Agreement or any Ancillary Agreement; or (iii) the gross negligence or willful misconduct of a Mylan Indemnatee under this Agreement or any Ancillary Agreement. Mylan’s obligation to Indemnify the Revance Indemnitees pursuant to this Section 13.1(b) shall be subject to Section 13.1(d) below and shall not apply to the extent that any such Liabilities result from clause (i), (ii), or (iii) in Section 13.1(a) above.

(c) **Procedure.** To be eligible to be Indemnified hereunder, the indemnified Person shall provide the indemnifying Party with prompt written notice of the Third-Party Claim giving rise to the indemnification obligation pursuant to this Section 13.1 and the right to control the defense (with the reasonable cooperation of the indemnified Person) or settlement any such claim; *provided, however*, that the indemnifying Party shall not enter into any settlement that admits fault, wrongdoing or damages without the indemnified Person’s written consent, such consent not to be unreasonably withheld or delayed. The indemnified Person shall have the right to join, but not to control, at its own expense and with counsel of its choice, the defense of any claim or suit that has been assumed by the indemnifying Party.

(d) **Intellectual Property Infringement Claims.** Notwithstanding the foregoing, the provisions set forth under Section 10.2 above shall govern the allocation of costs with respect to Defensive Actions (including any Defensive Actions under Section 10.2(d)) and declaratory judgment actions related thereto in the Mylan Territory that are covered by Section 10.2.

13.2 **Insurance.** Each Party shall, during the Term and for two (2) years after termination of this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company (*provided however* that either Party may satisfy all or part of its obligation through its insurance captive or self-insurance) product liability insurance providing protection against any and all claims, demands, and causes of action arising out of any defects, alleged or otherwise, of the Product or their use, design or manufacture, or any material incorporated in the Product. The amount of coverage shall be a minimum of [\*] combined single limit coverage for each occurrence for bodily injury or for property damage and shall be provided from an insurance company qualified to write global product liability coverage. Each Party agrees, upon request, to furnish the other Party with a certificate of insurance evidencing such insurance coverage (at the execution of this Agreement and at each subsequent renewal) and shall provide the other Party with a thirty (30) calendar day notice of cancellation or non-renewal of such coverage. Revance shall name Mylan as an additional insured on its insurance policies maintained pursuant to this Section 13.2.

## ARTICLE 14

### TERM & TERMINATION

14.1 **Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 14, shall remain in effect on a country-by-country basis until terminated in accordance with this Article 14 (the “**Term**”).

14.2 **Termination for Material Breach.** Subject to the further provisions of this Section 14.2, in the event of any material breach of this Agreement by a Party, the non-breaching Party shall have the right to serve notice upon the breaching Party of its intention to terminate this Agreement referencing this Section 14.2 and, unless the breaching Party cures such breach within [\*] calendar days of receipt of such notice, to terminate this Agreement. Such notice shall specify in reasonable detail the facts and circumstances constituting the material breach of this Agreement, as applicable. Upon the expiration of said [\*] calendar day period, if the breaching Party has not cured such material breach, then the non-breaching Party shall have the right to terminate this Agreement in its entirety, by giving a notice of such termination, which shall be effective on the date such notice is given. Notwithstanding the foregoing, in the event of a material breach of this Agreement [\*,] [\*] right to terminate in accordance with this Section 14.2 shall be [\*].

14.3 **Bankruptcy Event.** Notwithstanding anything to the contrary in this Agreement, this Agreement may be terminated in its entirety by either Party upon written notice if any Bankruptcy Event has occurred with respect to the other Party.

#### 14.4 **Termination by Mylan.**

(a) Mylan shall have the right to terminate this Agreement, in its entirety or with respect to any particular Region within the Mylan Territory, for any reason upon [\*] calendar days’ prior

written notice to Revance referencing this Section 14.4(a). From and after the effective date of such termination under this Section 14.4(a), with respect to a particular Region, the countries in such Region shall cease to be within the definition of “Mylan Territory,” for all purposes of this Agreement, and, except as otherwise provided for in this Agreement, all rights and obligations of Mylan with respect to such particular countries in such Region, as applicable, shall terminate.

(b) Mylan shall have the right to terminate this Agreement in accordance with Section 5.2(c) or 5.3(b).

(c) Mylan shall have the right to terminate this Agreement in accordance with Section 11.3(b).

14.5 **Termination by Revance.** Revance shall have the right to terminate this Agreement in accordance with Section 5.2(c), Section 5.3(b) and Section 11.3(b).

14.6 **Effects of Termination.**

(a) **General.** Upon termination of this Agreement in its entirety in accordance with this Agreement, this Agreement shall be of no further force or effect, neither Party shall have any further rights or obligations hereunder, and neither Party shall make any further use of any Collaboration Data, in each case except as otherwise provided herein (including as set forth in Section 14.1, 14.6(b) or 14.6(c) below). Termination of this Agreement for any reason shall not release any Party hereto from any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. Within [\*] calendar days of termination of this Agreement in its entirety for any reason, each Party shall destroy all tangible items comprising, bearing or containing trademarks, trade names, or Confidential Information of such other Party that is in its possession or Control; *provided* that each Party shall have the right to retain any such items or Confidential Information to the extent reasonably necessary to exercise any surviving rights or perform any surviving obligations and such items and Confidential Information shall remain subject to the protections of Article 12.

(b) **Termination (Reversion) with Continuing Product Rights for Revance.** Without limiting any other legal or equitable remedies that either Party may have, if (i) this Agreement is terminated by Mylan under Section 14.4(a) or 14.4(b), (ii) this Agreement is terminated by Revance under Section 14.2, 14.3 or 14.5, or (iii) a country becomes a Reverted Country pursuant to Section 7.1(c), the following provisions will take effect as of the effective date of such termination with respect to each Terminated Country or, solely to the extent such provisions are applicable to Reverted Countries, the effective date of such reversion with respect to a Reverted Country. For clarity, only the provisions below that are specified as applying to Reverted Countries shall apply with respect to Reverted Countries, in addition to Terminated Countries.

(i) Mylan shall use Commercially Reasonable Efforts, if requested by Revance in writing, to promptly transfer to Revance or its designee: (A) copies of all governmental and regulatory correspondence, conversation logs, Regulatory Filings or Marketing Authorizations reasonably necessary for and primarily related to the Development, manufacture or commercialization of the Product in the Terminated Country(ies) or Reverted Country(ies), as applicable, that are in Mylan’s possession or control

as of the effective date of such termination or reversion, as applicable; (B) copies of all data, reports, records and cell line materials that are developed hereunder, are in Mylan's possession or control as of the effective date of such termination or reversion, as applicable, and are reasonably necessary for and primarily related to the Development, manufacture or commercialization of the Product, including all non-clinical and clinical data relating to the Product developed hereunder ("**Mylan Data**"); and (C) all records and materials in Mylan's possession or control as of the effective date of such termination or reversion, as applicable, containing Confidential Information of Revance relating solely to the Terminated Country(ies) or Reverted Country(ies), as applicable; *provided, however*, that Mylan shall be entitled to retain one copy of all such Confidential Information for purposes of determining its obligations, and exercising any remaining rights, under this Agreement; and *provided further*, for clarity, that Mylan's obligations under this Section 14.6(b) shall not require Mylan to transfer any regulatory filings, regulatory approvals or related data or correspondence for a Competing Product of Mylan's, or any Product other than those licensed to Mylan hereunder, to Revance;

(ii) If, at the time of termination or reversion, as applicable, Mylan is then-currently performing process development or manufacturing activities for the Product in the Terminated Country(ies) or Reverted Country(ies), as applicable, Mylan shall upon Revance's written request for a reasonable period of time (not to exceed [\*] following receipt of written termination notice) and subject to Revance's agreement to reimburse Mylan for commercially reasonable internal and out-of-pocket costs and expenses associated therewith: (A) continue to perform such process development activities or manufacturing activities for the Product; and (B) use good faith efforts to effect a transfer of such activities to Revance or a Third Party on or before expiration of such [\*] transition period. If Revance so requests, Mylan will assign to Revance any agreements with Third Parties reasonably necessary for and primarily relating to the Development, manufacture or commercialization of the Product in the Terminated Country(ies) or Reverted Countries, as applicable, to which Mylan is a party to the extent permitted by the terms of such agreements; *provided, however*, that Mylan shall not be obligated to pay any amounts to the counterparty or to any Third Party in connection with such assignment;

(iii) The licenses granted to Mylan pursuant to Section 2.1(a) will terminate with respect to the Terminated Country(ies) or Reverted Country(ies), as applicable, (except to the extent necessary to enable Mylan to perform its obligations under this Section 14.6(b)), and Mylan shall (and hereby does) grant Revance (x) a perpetual, royalty-bearing (as set forth in this Section 14.6(b)(iii), except in the event this Agreement is terminated by Revance under Section 14.2 or Section 11.3(b)), non-exclusive, sublicensable license under the Mylan Technology Rights existing as of the date of termination and (y) a perpetual, exclusive (even as to Mylan), sublicensable license under Mylan Data generated pursuant to this Agreement and existing as of the date of termination or reversion, as applicable, in each case to Exploit the Product in the Terminated Country(ies) or Reverted Country(ies), as applicable, subject to the following payment obligations with respect to the Product in such countries, except in the event this Agreement is terminated by Revance under Section 14.2 or Section 11.3(b). Mylan shall not use, or authorize any other Person to use, the Mylan Data existing as of the date of termination to Develop, manufacture or commercialize the Product in the Terminated Country(ies) or Reverted Country(ies), as applicable.

(1) If the Agreement is terminated after [\*] and [\*], Revance shall pay to Mylan a royalty of [\*] of Net Sales of the Product by Revance or its Affiliates or licensees with respect to such Terminated Countries.



(2) The royalties due under this Section 14.6(b)(iii) shall be determined on a country-by-country basis beginning from the First Commercial Sale of the Product in such Terminated Country until Revance has paid to Mylan [\*] in the aggregate in royalties under this Section 14.6(b)(iii) (for clarity such cap is not on a country-by-country basis, but an aggregate amount across all countries).

(iv) Mylan will, upon Revance's written request, assign to Revance all right, title and interest in the trademark(s) specific to the Product and such Terminated Country(ies) or Reverted Country(ies), as applicable, and all goodwill associated therewith; provided that such assignment shall not include any Mylan corporate trademark or logo, or any derivative mark or variation thereof;

(v) Mylan will, as requested by Revance in writing and at Revance's sole cost and expense, reasonably cooperate with Revance, either to transition all Clinical Trials of the Product initiated prior to the effective date of termination or reversion, as applicable, that are specific to the Terminated Country or Reverted Country, as applicable, or to wind-down and end such Clinical Trials;

(vi) Mylan will, at Revance's request and sole cost and expense (including reimbursement of manufacturing costs) pursuant to a separate agreement to be negotiated by the Parties at the time of termination, transfer to Revance all inventory of Product produced hereunder that is in its possession as of the date of termination or reversion, as applicable, intended for Commercialization in the Terminated Country(ies) or Reverted Country(ies), as applicable;

(vii) In addition, Revance shall reimburse Mylan for commercially reasonable out-of-pocket expenses and FTE costs measured at the FTE Rate associated with the performance of the activities under subsections (i)- (vi) above; and

(viii) Mylan shall ensure that its Affiliates shall perform the obligations of Mylan under subsections (i) - (vi) where the power to perform such obligation is possessed or controlled by Mylan's Affiliates and not otherwise by Mylan.

(c) **Termination with Continuing Product Rights for Mylan.** Without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated by Mylan under Section 14.2, 14.3 or 14.4(c) after [\*], the following provisions will take effect as of the effective date of such termination with respect to the Terminated Countries:

(i) Revance will use Commercially Reasonable Efforts, if requested by Mylan in writing, to promptly transfer to Mylan or its designee: (A) copies of all governmental and regulatory correspondence, conversation logs, Regulatory Filings and Marketing Authorizations reasonably necessary for and primarily related to the Development, manufacture or commercialization of the Product in the Terminated Countries that are in Revance's possession or control as of the effective date of such termination; (B) copies of all data, reports, and records in Revance's possession or control as of the effective date of such termination that are reasonably necessary for and primarily related to the Development or commercialization of the Product, or the manufacture of Product, including all such non-clinical and clinical data relating to the Product ("Revance Data"); and (C) all records and materials in Revance's possession or control as of the effective date of such termination containing Confidential Information of Mylan relating to the Product; and provided further, for clarity, that the transfer obligations under this Section 14.6(c) shall not require Revance to transfer any regulatory approvals or related data or correspondence for a Competing Product of Revance's to Mylan;

(ii) Revance will, as requested by Mylan in writing and at Mylan's sole cost and expense, reasonably cooperate with Mylan, either to transition all Clinical Trials of the Product initiated prior to the effective date of such termination that are specific to the Terminated Countries or to wind-down and end such Clinical Trial;

(iii) Revance shall (and hereby does) grant Mylan (A) a perpetual, royalty-bearing, exclusive, sublicensable license under the Licensed Technology Rights existing as of the date of termination and (B) a perpetual, royalty-bearing (as set forth in this Section 14.6(c)(iii)), exclusive (even as to Revance), sublicensable license under Revance Data generated pursuant to this Agreement and existing as of the date of termination, in each case to Exploit the Product in the Terminated Countries, subject to the following payment obligations with respect to the Product in such countries. Revance shall not use, or authorize any other Person to use, the Revance Data generated pursuant to this Agreement and existing as of the date of termination to Develop, manufacture or commercialize the Product in the Terminated Countries.

(1) Subject to the Royalty Holiday with respect to Tier 1 Revenues, Mylan shall pay to Revance a royalty of [\*] of Net Sales of the Product by Mylan or its Affiliates or their Sublicensees in such Terminated Countries.

(2) The royalties due under this Section 14.6(c)(iii) shall be determined on a country-by-country basis beginning from the First Commercial Sale of the Product in such country until Mylan has paid royalties under this Section 14.6(c)(iii) to Revance in an amount equal to [\*], subject to an aggregate cap of [\*].

(iv) Revance will continue to supply Mylan with Biological Active Substance and, if being supplied as of the effective date of such termination, Product for the Terminated Countries in accordance with the Supply Agreement;

(v) Revance will, at Mylan's request and sole cost and expense (including reimbursement of manufacturing costs), transfer to Mylan all, or any requested portion, of the safety stock of Biological Active Substance in Revance's possession or control as of the effective date of termination;

(vi) In addition, Mylan shall reimburse Revance for commercially reasonable out-of-pocket expenses and FTE costs measured at the FTE Rate associated with the performance of the activities under subsections (i) and (ii) above; and

(vii) Revance shall ensure that its Affiliates shall perform the obligations of Revance under subsections (i) - (vi) where the power to perform such obligation is possessed or controlled by Revance's Affiliates and not otherwise by Revance.

14.7 **Reverted Countries.** Without limiting the foregoing, in the event of a partial termination hereunder, Revance shall continue to owe to Mylan a percentage of Reverted Country Product Revenues from each Reverted Country on a quarterly basis in accordance with Section 7.1(c); provided that in the event this Agreement is terminated in its entirety, all Reverted Countries shall become Terminated Countries such that Revance shall instead pay to Mylan the royalties set forth in Section 14.6(b)(iii) with respect to such countries.

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

14.9 **Survival.** Article 1 (Definitions), Article 8 (Payments) (with respect to any payments due prior to the effective date of termination), Article 9 (Payment Terms) (with respect to any payments due prior to the effective date of termination), Article 12 (Confidentiality), Article 13 (Indemnification; Insurance), Article 15 (Dispute Resolution), and Article 16 (Miscellaneous) and Sections 11.4(g), 5.4 (Branded Alternative), 11.5 (Disclaimer), 14.6 (Effects of Termination), 14.7 (Reverted Countries), 14.8 (Nonexclusive Remedy), and 14.9 (Survival) shall survive any termination of this Agreement. Upon the termination of this Agreement for any reason, [\*], *provided* that [\*].

## ARTICLE 15

### DISPUTE RESOLUTION

15.1 **Senior Executives.** Except as otherwise provided herein (including in Sections 4.5 and 4.8), any dispute, controversy or claim arising under, out of or in connection with this Agreement, including any subsequent amendments, or the validity, enforceability, construction, performance or breach hereof (and including the applicability of this Article 15 to any such dispute, controversy or claim) (each a “**Dispute**”) shall be first submitted to the Senior Executives for attempted resolution by good faith negotiations within ten (10) Business Days. In such event, each Party shall cause its Senior Executives to meet and be available to attempt to resolve such issue. If the Senior Executives should resolve such Dispute, a memorandum setting forth their agreement will be prepared and signed by both Parties if requested by either Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the Dispute.

15.2 **Jurisdiction.** The Parties agree that any Dispute that is not resolved pursuant to Section 15.1 shall be subject to the exclusive jurisdiction of [\*] and each Party hereby submits to such jurisdiction.

## ARTICLE 16

### MISCELLANEOUS

16.1 **LIMITATION OF LIABILITY.** EXCEPT WITH RESPECT TO LIABILITY RESULTING FROM A PARTY’S FRAUD OR WILLFUL MISCONDUCT OR ANY BREACH OF SECTION 2.4 OR ARTICLE 12, OR AS MAY BE PAYABLE PURSUANT TO THE APPLICABLE PARTY’S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT OR PURSUANT TO SECTION 10.2(d), TO THE MAXIMUM EXTENT PERMITTED BY LAW AND NOTWITHSTANDING ANY PROVISION IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, RELIANCE OR PUNITIVE DAMAGES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY

REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE. THE PARTIES AGREE THAT THE LIMITATIONS SPECIFIED IN THIS SECTION SHALL APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THIS AGREEMENT IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. FURTHER, THE FOREGOING SHALL NOT LIMIT EITHER PARTY'S OBLIGATIONS WITH RESPECT TO LITIGATION COSTS COVERED BY ARTICLE 10, INCLUDING SUCH COSTS ASSOCIATED WITH LEGAL CLEARANCE ACTIVITIES OR DEFENSIVE ACTIONS OF THE PRODUCT IN THE MYLAN TERRITORY.

16.2 **Relationship of the Parties.** The Parties agree that the relationship of Revance and Mylan established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish a partnership or joint venture, and nor shall this Agreement create or establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

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

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

16.5 **Force Majeure.** No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement, but only to the extent that such failure or delay is due to causes beyond the reasonable control of the affected Party, including: (a) acts of God; (b) fire, explosion, or unusually severe weather; (c) war, invasion, riot, terrorism, or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargo or blockages; (e) national or regional emergency; (f) strikes or industrial disputes at a national level which directly impact the affected Party's performance under this Agreement; or (g) other similar cause outside of the reasonable control of such Party ("**Force Majeure**"); *provided* that the Party affected shall promptly notify the other of the Force Majeure condition and shall eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible. If the performance of any obligation of a Party under this Agreement is delayed owing to such a Force Majeure for any continuous period of more than [\*] calendar days, the other Party shall have the right to terminate this Agreement.

16.6 **Further Assurances.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the express purposes and intent of this Agreement, as reasonably requested by the other Party.

16.7 **Notices.** Any notice required or permitted to be given hereunder shall be in writing and shall be delivered in person, by a nationally recognized overnight courier, or by registered or certified airmail, postage prepaid, to the addresses given below or such other addresses as may be designated in

writing by the Parties from time to time during the Term, and shall be deemed to have been given three (3) Business Days after sending same.

**In the case of Revance:**

Revance Therapeutics, Inc.  
7555 Gateway Boulevard  
Newark, California 94560  
Attention: Chief Executive Officer

**In the case of Mylan:**

Mylan Ireland Ltd.  
c/o Mylan Inc.  
1000 Mylan Boulevard  
Canonsburg, PA 15317 U.S.A.  
Attention:

**With a required copy to:**

Revance Therapeutics, Inc.  
7555 Gateway Boulevard  
Newark, California 94560  
Attention: Legal Department

**With a required copy to:**

Mylan Inc.  
1000 Mylan Boulevard  
Canonsburg, PA 15317 U.S.A.  
Attention: Global General Counsel

16.8 **Assignment.**

(a) **Rights to Assign.** Neither Party shall at any time, without obtaining the prior written consent of the other Party, assign or transfer this Agreement or subcontract (except as permitted under this Agreement) its obligations hereunder to any Person. Notwithstanding the foregoing, either Party shall be permitted, without the consent of the other Party, to assign this Agreement to its Affiliates or to perform this Agreement, in whole or in part, through its Affiliates, and either Party may also assign this Agreement, without the consent of the other Party, to an Affiliate or any successor or Third Party that acquires all or substantially all of the assets to which this Agreement relates or the equity of such Party, by sale, transfer, merger, reorganization, operation of law or otherwise (a “**Sale Transaction**”); *provided* that the assignee agrees in writing to be bound to the terms and conditions of this Agreement where not bound by the operation of law. In the event of an assignment permitted under this Section 16.8, the assigning Party shall notify the other Party in writing of such assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns. Any assignment not in accordance with this Section 16.8 shall be null and void.

(b) **Subsequent Sale or Acquisition.** In the event of (x) a Sale Transaction of Revance by a Third Party, or (y) the acquisition by Revance of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, a “**Revance Acquiree**”), whether by merger, sale of stock, sale of assets or otherwise (a “**Revance Acquisition**”), the following shall apply: (i) intellectual property rights of the acquiring party in a Sale Transaction (together with any entities that were affiliates of such Third Party immediately prior to such Sale Transaction, a “**Third Party Acquirer**”), or the Revance Acquiree, as applicable, shall not be included in the technology licensed hereunder or otherwise subject to this Agreement, and (ii) [\*] with respect to [\*].

(c) **Change of Control.**

(i) Notwithstanding anything to the contrary herein, in the event that Revance is subject to a Change of Control (whether or not this Agreement is assigned in connection with such Change of Control), Revance shall, within [\*] Business Days after the date that such Change of Control closes, provide Mylan with notice of such Change of Control.

(ii) In the event that a Change of Control occurs prior to [\*], then Mylan shall have the right to elect to [\*] and, upon such election, Mylan shall [\*] and Mylan shall [\*], and Revance shall [\*]. Accordingly, Revance shall [\*], except to the extent that [\*]. Revance shall [\*] and [\*].

(iii) Following a Change of Control, Revance shall [\*] in accordance with this Agreement [\*]; provided that, in the case of [\*], upon Mylan's request, Revance shall (1) [\*], and (2) [\*]. [\*] Revance will continue to [\*]. [\*], Revance shall [\*]. If Mylan elects to [\*], then [\*] with respect to [\*] shall be [\*] as expressly set forth in this Section 16.8(c)(iii).

(iv) **Change of Control Definition.** For purposes of the foregoing, a “**Change of Control**” shall mean, with respect to Revance, the occurrence of any of the following events: (1) the sale, transfer, conveyance or other disposition of all or a majority of the assets of the Revance to a Third Party; or (2) the acquisition of beneficial ownership, directly or indirectly, by a Third Party of common shares or other equity interest representing more than fifty percent (50%) of the aggregate ordinary voting power represented by the issued and outstanding common shares or other equity interests of Revance; or (3) a merger, reorganization or consolidation involving Revance in which the stockholders of Revance, immediately prior to the merger, reorganization or consolidation, would not, immediately after the merger, reorganization or consolidation, beneficially own, directly or indirectly, shares representing in the aggregate more than fifty percent (50%) of the combined ordinary voting power of the resulting ultimate parent company; *provided* that neither of the following shall constitute a Change of Control: (i) a transaction or series of transactions in which (A) a majority of the members of the Board of Directors of Revance prior to such transaction or series of transactions remain members of the Board of Directors of the resulting parent company following such transaction(s) and represent a majority of that Board of Directors and (B) a majority of the members of the senior management of Revance remain in senior management positions at resulting parent company following the transaction or series of transactions; or (ii) a public offering of equity securities of Revance or any Affiliate of Revance pursuant to an effective registration statement under the Securities Act of 1933, as amended. The “**Acquiring Entity**” means the acquiring or resulting entity in such transaction.

16.9 **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of [\*] without reference to conflicts of laws principles.

16.10 **Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement from Revance to Mylan are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any non-U.S. equivalent thereof, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. Revance agrees that Mylan, as exclusive licensee of certain rights and licenses under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any non-U.S. equivalent thereof. Revance further agrees that, in the event of the commencement of a bankruptcy proceeding by or against Revance under the U.S.

Bankruptcy Code or other Applicable Law governing Revance, Mylan shall have the right to retain any and all rights and licenses granted to it hereunder, to the maximum extent permitted by Applicable Law (such as under Sections 365(n)(1) and 365(n)(2) of the U.S. Bankruptcy Code or any non-U.S. equivalent thereof) and be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Mylan's possession, shall be promptly delivered to it upon any such commencement of a bankruptcy proceeding, unless Revance (or its bankruptcy trustee) elects to assume this Agreement and continue to perform all of its obligations under this Agreement.

16.11 **Entire Agreement and Amendment.** This Agreement (including, for clarity, its Exhibits and the Ancillary Agreements), constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior and contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. Notwithstanding the foregoing, except to the extent expressly set forth herein, to the extent the terms and conditions of the body of this Agreement conflict with the terms and conditions of any Exhibit hereto, the terms and conditions of the body of this Agreement shall govern. No terms or conditions of this Agreement will be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

16.12 **No Third Party Beneficiaries.** Except for the rights to indemnification provided for under Article 13 above, all rights, benefits and remedies under this Agreement are solely intended for the benefit of Revance and Mylan, and except for such rights to indemnification expressly provided pursuant to Article 13, no Third Party shall have any rights whatsoever to: (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

16.13 **Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to negotiate in good faith a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

16.14 **No Waiver.** A waiver by any Party of any of the terms and conditions of this Agreement in any instance will not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement will be cumulative and none of them will be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

16.15 **Compliance with Laws.** Both Revance and Mylan shall perform their obligations under this Agreement in accordance with Applicable Law and each Party shall bear its own costs in ensuring compliance therewith. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement that violates, or which it reasonably believes may violate, any Applicable Law.

16.16 **English Language.** This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

16.17 **Review by Legal Counsel.** Each Party agrees that it has read and had the opportunity to review this Agreement with its legal counsel. Accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

16.18 **Further Acts.** Each Party shall do, execute and perform and shall procure to be done and perform all such further acts, deeds, documents and things as the other Parties may reasonably require from time to time to give full effect to the terms of this Agreement.

16.19 **Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same document. This Agreement and any amendments hereto, to the extent signed and delivered by means of electronic reproduction (*e.g.*, portable document format (.pdf)), shall be treated in all manner and respects as an original and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person. At the request of a Party, the other Party shall re-execute original forms thereof and deliver them to the Party who made said request.

*{The remainder of this page is left intentionally blank.}*



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

REVANCE THERAPEUTICS, INC.

By: /s/ L. Daniel Browne  
Name: L. Daniel Browne  
Title: President and Chief Executive Officer

MYLAN IRELAND LTD.

By: /s Peter McCormick  
Name: Peter McCormick  
Title: Global Head OSD Operations

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

## EXHIBITS

Exhibit 1.7 Biological Active Substance

Exhibit 1.12 Cell Line

Exhibit 1.31 Financial Exhibit (with confirmatory signatures)

Exhibit 1.44 Licensed Materials

Exhibit 1.45 Licensed Patents

Exhibit 4.3 Initial JSC Members

Exhibit 5.2 Initial Development Plan

Exhibit 7.2(a) Supply Agreement

Exhibit 11.2(d) Third Party Contracts

Exhibit 12.5 Joint Press Release

Exhibit 13.2 Revance Certificate of Insurance

**Exhibit 1.7**

**Biological Active Substance**

**The Biological Active Substance (BAS) is [\*]**

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

**Exhibit 1.12**

**Cell Line**

The cell line is [\*], also known as [\*].

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

## Exhibit 1.31

### **Financial Exhibit**

1. **Initial Payment.** In consideration for the rights and licenses granted by Revance to Mylan under this Agreement, within [\*] calendar days after the Effective Date, Revance shall issue an invoice to Mylan for, and Mylan shall pay to Revance, Twenty-Five Million Dollars (US\$25,000,000) (“**Upfront Payment**”).

2. **FDA Advisory Milestone Payment.** If Mylan provides Revance with a Continuation Notice, in accordance with Section 5.2(c), that it will continue with development of the Product for the Mylan Territory under this Agreement, Revance shall issue to Mylan an invoice for [\*] (the “**FDA Advisory Milestone Payment**”), as well as an amount equal to [\*] any Excess Revance Costs, and Mylan shall pay such invoice within [\*] calendar days of receipt.

3. **Contingent Development Milestone Payments.** Mylan shall provide Revance with written notice within [\*] Business Days of the first achievement of each development milestone event set forth below by Mylan, its Affiliate or Sublicensee with respect to the Product hereunder, and, upon receipt of each such notice, Revance shall issue Mylan an invoice for the corresponding milestone payment amount set forth below. Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance the milestone payments amounts set forth below within [\*] calendar days after receipt of an invoice for such amount from Revance, provided in accordance with this paragraph 3. Each milestone payment by Mylan to Revance under this paragraph 3 shall be payable only once and in no event shall the aggregate amount to be paid by Mylan under this paragraph 3 exceed [\*].

#### Development Milestone Event

[\*]

#### Milestone Payment

[\*]

In the event that a milestone payment with respect to milestone event [\*] has not been paid at such time as milestone event [\*] is achieved, then Mylan shall pay Revance such unpaid milestone payment with respect to milestone event [\*] along with its payment for the first of such later milestone events ([\*]) to occur. In the event that a milestone payment with respect to milestone event [\*] has not been paid at such time as milestone event [\*] is achieved, then Mylan shall pay Revance such unpaid milestone payment with respect to milestone event [\*] along with its payment for milestone event [\*]. In the event that a milestone payment with respect to milestone event [\*] has not been paid at such time as a milestone event [\*] is achieved, then Mylan shall pay Revance such unpaid milestone payment with respect to milestone event [\*] along with its payment for milestone event [\*].

4. **Contingent Commercial Milestone Payments.** Mylan shall provide Revance with written notice of the first achievement of each commercial milestone event set forth below by Mylan, its Affiliate or Sublicensee with respect to the Product hereunder, within [\*] Business Days with respect to commercial milestone events [\*] and within [\*] days of the end of the calendar year in which such milestone occurred with respect to commercial milestone events [\*]. Upon receipt of each such notice, Revance shall issue Mylan an invoice for the corresponding milestone payment set forth below. Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses

granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance the milestone payment amounts set forth below within [\*] calendar days after receipt of an invoice for such amount from Revance, provided in accordance with this paragraph 4. Each milestone payment by Mylan to Revance under this paragraph 4 shall be payable only once and in no event shall the aggregate amount to be paid by Mylan under this paragraph 4 exceed Two Hundred Twenty-Five Million Dollars (\$225,000,000).

**Commercial Milestone Event**

[\*]

**Milestone Payment**

[\*]

5. **Royalties.**

(a) **U.S. Royalties.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance royalties on U.S. Annual Product Revenues during the Term, as calculated by multiplying the applicable Royalty Rate by the corresponding portion of incremental U.S. Annual Product Revenues set forth in the table below:

<b>Annual Product Revenue Level</b>	<b>Royalty Rate</b>
For that portion of U.S. Annual Product Revenues less than \$50,000,000 (“ <b>Tier 1 Revenues</b> ”), subject to the Royalty Holiday	[*]
For that portion of U.S. Annual Product Revenues greater than or equal to \$50,000,000 but less than [*]	[*]
For that portion of U.S. Annual Product Revenues greater than or equal to [*]	[*]

Notwithstanding the foregoing, royalties on Tier 1 Revenues will commence upon the expiration of the Royalty Holiday, and no royalties shall be owed with respect to Tier 1 Revenues that occur during the Royalty Holiday. For purposes of the foregoing, the “**Royalty Holiday**” means the period commencing on First Commercial Sale of the Product in the U.S. by Mylan or its Affiliate or Sublicensee and expiring upon the expiration of the fourth Net Sales Calendar Year. “**Net Sales Calendar Year**” means each of (a) (i) the year in which the First Commercial Sale of the Product is made in the U.S. by Mylan or its Affiliate or Sublicensee, if such First Commercial Sale is made on or before March 31st of the applicable calendar year or (ii) the first full calendar year following the date on which the First Commercial Sale of the Product is made in the U.S. by Mylan or its Affiliate or Sublicensee, if such First Commercial Sale is made after March 31st of the applicable calendar year ((i) or (ii), the “**First Net Sales Calendar Year**”), and (b) each of the three calendar years immediately following the First Net Sales Calendar Year.

(b) **European Royalties.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance royalties on European Product Revenues during the Term, equal to [\*] of European Product Revenues. Notwithstanding the foregoing or paragraph 5(c), the Parties shall discuss in good faith any tender opportunities in Europe or any country in the Mylan Territory outside of the U.S. and Europe, including any adjustments to the royalties set forth in this paragraph 5(b) reasonably necessary to enable Mylan, its Affiliate or Sublicensees to competitively bid for such tenders.

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

(c) **Rest of World Royalties.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, Mylan shall pay to Revance royalties on ROW Product Revenues during the Term, equal to [\*] of ROW Product Revenues.

(d) **Royalty Reports and Payment.** Subject to the terms and conditions of this Agreement and in further consideration for the rights and licenses granted by Revance to Mylan under this Agreement, within [\*] calendar days after the end of each calendar quarter following the First Commercial Sale of the Product in the Mylan Territory and then each calendar quarter thereafter, Mylan shall provide to Revance a true and accurate report setting out in reasonable detail (including on a country-by-country basis where applicable) the information necessary to calculate royalty payments due under this paragraph 5 above with respect such calendar quarter, including: (i) gross sales of the Product in the relevant calendar year; (ii) Net Sales of the Product by Mylan or its Affiliates in the relevant calendar quarter; and (iii) the date of First Commercial Sale of the Product in any country in the Mylan Territory first occurring during such calendar quarter (each, a **“Royalty Report”**). Simultaneously with the delivery of each Royalty Report, Mylan shall pay to Revance the total amounts due under this paragraph 5 above for the period covered by such Royalty Report. Within fifteen (15) calendar days after the end of each calendar quarter, Mylan shall, for informational purposes only, provide to Revance a non-binding estimate of the royalty payable.

(e) **Anti-Stacking.** Mylan shall be entitled to credit against the royalties owed by Mylan to Revance pursuant to this paragraph 5 up to [\*] of any royalties paid by a Selling Party to Third Parties on sales of Products in consideration for licenses under patent rights owned or controlled by such Third Party that cover the Product subject to Revance’s consent, not to be unreasonably withheld, delayed or conditioned; *provided* that in no event shall such credit reduce the royalty rates set forth in this paragraph 5 by more than [\*].

## 6. **Development Cost Sharing.**

(a) **Sharing.** The Parties shall share Development Costs for the Product in accordance with Section 5.3(d) of the Agreement.

(b) **Reporting and Reconciliation.** Within [\*] calendar days after the end of each calendar quarter during which activities are being performed under the Initial Development Plan or the Development Plan, each Party shall report to the other the Development Costs incurred by such Party during such calendar quarter (each, an **“Initial Development Cost Report”**), in sufficient detail for Mylan to track Revance’s Development Costs against the Initial Development Cap, and for each Party to track Development Costs against the Continued Development Cap. Without limiting Section 9.4 of the Agreement, each Party shall keep complete and accurate records of its Development Costs incurred in the performance of the Initial Development Plan or the Development Plan, as applicable, and such records shall be made available to the other Party to verify the Development Costs reported each quarter. Within [\*] days of its receipt of Revance’s Initial Development Cost Report for each quarter, Mylan shall (a) reconcile each Party’s Initial Development Cost Report to (i) ensure that each Party is bearing fifty percent (50%) of the Development Costs incurred by the Parties during such quarter in accordance with the Development Budget and (ii) review aggregate Development Costs incurred in accordance with the Initial Development Plan and the Development Budget against the Initial Development Cost Cap and the

Continued Development Cost Cap, respectively; and (b) issue a report setting forth (i) any payment owed by one Party to the other Party to ensure that each Party is bearing its agreed upon share of Development Costs (as set forth in Article 5), (ii) aggregate Development Costs incurred by the Parties in (1) the performance of the Initial Development Plan and (2) the performance of the Development Plan in accordance with the Development Budget (such report, the “**Reconciliation Report**”). If the Reconciliation Report reveals that Mylan has paid more than its fifty percent (50%) share of Development Costs incurred in accordance with the Development Budget during such calendar quarter, Mylan shall issue to Revance, together with the Reconciliation Report, an invoice in the amount necessary to ensure that each Party bears fifty percent (50%) of such Development Costs. If the Reconciliation Report reveals that Revance has paid more than its fifty percent (50%) share of Development Costs incurred in accordance with the Development Budget during such calendar quarter, Revance shall issue to Mylan, upon receipt of such Reconciliation Report, an invoice in the amount necessary to ensure that each Party bears fifty percent (50%) of such Development Costs. Invoices issued pursuant to this paragraph 6 shall be paid within [\*] days of receipt.

7. **Signatures for Confirmation Only.** This Financial Exhibit is an exhibit to, and an integral part of, the Exclusive License and Commercialization Agreement between Mylan Ireland Ltd. and Revance Therapeutics, Inc., dated February 28, 2018, and is subject to all the terms and conditions set forth therein. This Financial Exhibit is not intended to be, and shall not be construed to be, a separate agreement. The signatures below indicate confirmation that the financial terms set forth in this Financial Exhibit reflect applicable financial terms of such Agreement.



REVANCE THERAPEUTICS, INC.

By: /s/ L. Daniel Browne  
Name: L. Daniel Browne  
Title: President and Chief Executive Officer

MYLAN IRELAND LTD.

By: /s/ Peter McCormick  
Name: Peter McCormick  
Title: Global Head OSD Operations

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

**Exhibit 1.44**

**Licensed Materials**

Revanca licensed the following materials for the research and manufacture of its products:

[\*]

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**Exhibit 1.45**

**Licensed Patents**

[\*]

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### **Exhibit 4.3**

#### **Initial JSC Members**

**For Revance:**

- Chief Operating Officer
- Head of R&D
- Head of Regulatory

**Mylan will provide Revance separately with a list of its initial JSC members.**

**Exhibit 5.2**

**Initial Development Plan**

[\*] (6 pages omitted)

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

**Exhibit 7.2(a)**  
**Supply Agreement**

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

**Exhibit 11.2(d)**

**Third Party Contract(s)**

[\*]

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

**Exhibit 12.5**

**Joint Press Release**

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



**Exhibit 13.2**

**Revance Certificate of Insurance**

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

CERTIFICATIONS

I, L. Daniel Browne, certify that:

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

Date: May 9, 2018

/s/ L. Daniel Browne

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L. Daniel Browne  
President and Chief Executive Officer  
(Principal Executive Officer)

CERTIFICATIONS

I, Lauren P. Silvermail, certify that:

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

Date: May 9, 2018

/s/ Lauren P. Silvermail

Lauren P. Silvermail

Chief Financial Officer and Chief Business Officer  
(Principal Financial Officer)

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), L. Daniel Browne, Chief Executive Officer of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2018

**IN WITNESS WHEREOF**, the undersigned has set his hands hereto as of the 9th day of May, 2018.

/s/ L. Daniel Browne

\_\_\_\_\_

L. Daniel Browne

President and Chief Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Lauren P. Silvernail, Chief Financial Officer of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2018

**IN WITNESS WHEREOF**, the undersigned has set her hands hereto as of the 9th day of May, 2018.

/s/ Lauren P. Silvernail

\_\_\_\_\_  
Lauren P. Silvernail

Chief Financial Officer and Chief Business Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.