Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from to

Commission file number: 001-36033

THERAVANCE BIOPHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Cayman Islands (State or Other Jurisdiction of Incorporation or Organization)	**98-1226628** (I.R.S. Employer Identification No.)
PO Box 309 **Ugland House, South Church Street** **George Town, Grand Cayman, Cayman Islands** (Address of Principal Executive Offices)	**KY1-1104** (Zip Code)

(650) 808-6000
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

As of August 1, 2016, the number of the registrant's outstanding ordinary shares was 47,851,848.

THERAVANCE BIOPHARMA, INC.
TABLE OF CONTENTS

	Page No.
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015 (unaudited)	3
Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2016 and 2015 (unaudited)	4
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015 (unaudited)	5
Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	23
Item 4. Controls and Procedures	23
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	24
Item 1A. Risk Factors	24
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	50
Item 6. Exhibits	51
Signatures	52
Exhibit Index	53

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except per share data)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 148,363	$ 112,707
Short-term marketable securities	101,316	59,727
Accounts receivable, net of allowances of $1,238 and $758 at June 30, 2016 and December 31, 2015, respectively	1,856	1,922
Receivables from collaborative arrangements	35,080	35,232
Prepaid taxes	3,150	12,764
Other prepaid and current assets	3,550	5,115
Inventories	9,810	10,005
Total current assets	303,125	237,472
Property and equipment, net	8,811	9,873
Long-term marketable securities	52,316	42,860
Other investments	8,000	8,000
Restricted cash	833	833
Other assets	1,403	1,078
Total assets	$ 374,488	$ 300,116
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 7,412	$ 18,804
Accrued personnel-related expenses	9,020	10,866
Accrued clinical and development expenses	22,650	14,709
Other accrued liabilities	4,913	4,947
Deferred revenue	662	144
Total current liabilities	44,657	49,470
Deferred rent	4,369	4,598
Other long-term liabilities	3,878	2,983
Commitments and contingencies (Note 9)		
Shareholders' equity		
Preferred shares, $0.00001 par value: 230 shares authorized, no shares issued or outstanding at June 30, 2016 and December 31, 2015, respectively	—	—
Ordinary shares, $0.00001 par value: 200,000 shares authorized at June 30, 2016 and December 31, 2015; 47,853 and 37,981 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	732,334	564,691
Accumulated other comprehensive income (loss)	181	(70)
Accumulated deficit	(410,931)	(321,556)
Total shareholders' equity	321,584	243,065
Total liabilities and shareholders' equity	$ 374,488	$ 300,116

See accompanying notes to condensed consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue:				
Product sales	$ 5,359	$ 2,124	$ 8,670	$ 3,404
Revenue from collaborative arrangements	112	5,010	15,211	24,131
Total revenue	5,471	7,134	23,881	27,535
Costs and expenses:				
Cost of goods sold	638	505	1,416	875
Research and development (1)	32,069	30,377	67,748	66,396
Selling, general and administrative (1)	20,261	21,545	43,857	43,293
Total costs and expenses	52,968	52,427	113,021	110,564
Loss from operations	(47,497)	(45,293)	(89,140)	(83,029)
Interest and other income	308	204	495	414
Loss before income taxes	(47,189)	(45,089)	(88,645)	(82,615)
Provision for income taxes	36	2,514	730	7,463
Net loss	$ (47,225)	$ (47,603)	$ (89,375)	$ (90,078)
Net loss per share:				
Basic and diluted net loss per share	$ (1.06)	$ (1.42)	$ (2.16)	$ (2.71)
Shares used to compute basic and diluted net loss per share	44,407	33,532	41,366	33,183
Net unrealized gain (loss) on available-for-sale investments	55	(7)	251	107
Total comprehensive loss	$ (47,170)	$ (47,610)	$ (89,124)	$ (89,971)

(1) Amounts include share-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2016	2015	2016	2015
Research and development	$ 4,959	$ 6,817	$ 10,119	$ 14,299
Selling, general and administrative	4,945	7,845	11,115	15,989
Total share-based compensation expense	$ 9,904	$ 14,662	$ 21,234	$ 30,288

See accompanying notes to condensed consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	$ (89,375)	$ (90,078)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,153	1,572
Share-based compensation	21,234	30,289
Inventory write-down	119	79
Excess tax benefits from share-based compensation	—	(240)
Changes in operating assets and liabilities:		
Accounts receivable	66	(516)
Receivables from collaborative arrangements	152	(23,647)
Prepaid taxes	9,614	(3,024)
Other prepaid and current assets	1,566	(1,286)
Inventories	157	359
Other assets	711	(511)
Accounts payable	(10,757)	(3,770)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	5,732	(13,208)
Deferred rent	(229)	(255)
Deferred revenue	905	385
Other long-term liabilities	508	723
Net cash used in operating activities	(58,444)	(103,128)
Investing activities		
Purchases of property and equipment	(1,322)	(1,367)
Purchases of marketable securities	(91,382)	(11,059)
Maturities of marketable securities	40,514	95,879
Net cash (used in) provided by investing activities	(52,190)	83,453
Financing activities		
Net proceeds from sale of ordinary shares	145,224	27,310
Proceeds from ESPP purchases	1,944	—
Proceeds from option exercise	1,346	—
Excess tax benefits from share-based compensation	—	240
Repurchase of shares to satisfy tax withholding	(2,224)	—
Net cash provided by financing activities	146,290	27,550
Net increase in cash and cash equivalents	35,656	7,875
Cash and cash equivalents at beginning of period	112,707	89,215
Cash and cash equivalents at end of period	$ 148,363	$ 97,090
Supplemental disclosure of cash flow information		
Cash (received) paid for income taxes, net	$ (9,488)	$ 7,273

See accompanying notes to condensed consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of Operations and Summary of Significant Accounting Policies

Description of Operations

Theravance Biopharma, Inc. ("Theravance Biopharma", the "Company", or "we" and other similar pronouns) is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinases ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

Basis of Presentation

The Company's condensed consolidated financial information as of June 30, 2016, and the three and six months ended June 30, 2016 and 2015 are unaudited but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of the financial position at such date and of the operating results and cash flows for those periods, and have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated December 31, 2015 financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission ("SEC") on March 11, 2016.

Significant Accounting Policies

There have been no material revisions in our significant accounting policies described in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Recently Issued Accounting Pronouncements Not Yet Adopted

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which will replace most existing revenue recognition guidance in GAAP when it becomes effective. ASU 2014-19's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under the currently effective guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. ASU 2014-09 was initially to be effective for interim and annual reporting periods beginning after December 15, 2016. In August 2015, the FASB issued ASU 2015-14 which delays the effective date of ASU 2014-09 by one year and allows for early adoption as of the original effective date. In March 2016, the FASB issued ASU 2016-08 which clarifies

certain principal versus agent considerations under *Topic 606*. In April 2016, the FASB issued ASU 2016-10 which clarifies *Topic 606's* implementation guidance on identifying performance obligations in a contract and determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). In May 2016, the FASB issued ASU 2016-12 which amends the guidance on transition, collectability, noncash consideration and the presentation of sales and other similar taxes. ASU 2016-12 clarifies that, for a contract to be considered completed at transition, all (or substantially all) of the revenue must have been recognized under legacy GAAP. In addition, ASU 2016-12 clarifies how an entity should evaluate the collectability threshold and when an entity can recognize nonrefundable consideration received as revenue if an arrangement does not meet the standard's contract criteria.

The effective dates of ASU 2016-08, ASU 2016-10, and ASU 2016-12 are the same as the new effective date of ASU 2014-09 which is for all interim and annual reporting periods beginning after December 15, 2017, and early adoption is permitted as of the original effective date of ASU 2014-09. We currently do not anticipate an early adoption of the new revenue standards, and we are currently evaluating the impact that the adoption of the new revenue standards will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for all interim and annual reporting periods beginning after December 15, 2018 with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718)* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as equity or liabilities, an option to recognize gross share compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. ASU 2016-09 is effective for all interim and annual reporting periods beginning after December 15, 2016 with early adoption permitted. We are currently evaluating the potential impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

In May 2016, the FASB issued ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815)* ("ASU 2016-11"). With respect to *Revenue Recognition* (*Topic 605),* ASU 2016-11 rescinds various standards codified as part of *Revenue Recognition (Topic 605)* in relation to the future adoption of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. These rescissions include changes to topics pertaining to revenue and expense recognition for freight services in process, accounting for shipping and handling fees and costs and accounting for consideration given by a vendor to a customer. ASU 2016-11 was effective immediately upon issuance and will be adopted when we adopt ASU 2014-09. We are currently evaluating the impact that the adoption of ASU 2016-11, specific to *Topic 605*, will have on our consolidated financial statements and related disclosures. We do not believe ASU 2016-11, specific to *Topic 815*, will have any material impact on our consolidated financial statements and related disclosures.

2. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares outstanding, less ordinary shares subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares outstanding, less ordinary shares subject to forfeiture, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities.

For the three and six months ended June 30, 2016 and 2015, diluted and basic net loss per share was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

Anti-Dilutive Securities

The following common equivalent shares were not included in the computation of diluted net loss per share because their effect was anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2016**	**2015**	**2016**	**2015**
Share issuances under equity incentive plan and ESPP	3,310	6,684	3,417	4,404
Restricted shares	1,488	260	1,488	260
	4,798	6,944	4,905	4,664

3. Collaborative Arrangements

Revenue from Collaborative Arrangements

We recognized the following revenues from our collaborative arrangements:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	**2016**	**2015**	**2016**	**2015**
Mylan	$ 25	$ 25	$ 15,051	$ 19,124
R-Pharm	18	2,009	27	2,031
SciClone Pharmaceuticals	2	2,950	4	2,950
Other	67	26	129	26
Total revenue from collaborative arrangements	$ 112	$ 5,010	$ 15,211	$ 24,131

Mylan

Development and Commercialization Agreement

In January 2015, we established a strategic collaboration with Mylan Ireland Limited ("Mylan") for the development and, subject to regulatory approval, commercialization of revefenacin (TD-4208), our investigational LAMA in development for the treatment of COPD. We entered into this collaboration to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV.

In the first quarter of 2015, upfront payments totaling $19.2 million from Mylan were allocated to the license and committee participation deliverables based on the relative selling price method. The $19.2 million consisted of the initial payment of $15.0 million in cash and the $4.2 million premium related to the equity investment, which represents the difference between the closing price on January 30, 2015 and the issued price of $18.918 per share. For the six months ended June 30, 2015, we recognized $19.1 million in revenue from the Mylan collaborative arrangement related primarily to the license and technological know-how delivered in the first quarter of 2015.

For the three months ended June 30, 2016, we recognized $25,000 for the amortization of previously deferred revenue. For the six months ended June 30, 2016, we recognized $15.1 million in revenue, primarily related to the $15.0 million milestone payment received from Mylan for the achievement of 50% enrollment in the Phase 3 twelve-month safety study.

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the "Takeda Agreement") with Millennium Pharmaceuticals, Inc. ("Millennium"), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Prior to the Takeda Agreement, the Company has developed TD-8954 for potential use in the treatment of gastrointestinal motility disorders, including short-term intravenous use for enteral feeding intolerance ("EFI") to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received U.S. Food and Drug Administration ("FDA") Fast Track Designation. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502) (collectively with Millennium, "Takeda"). Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. We will receive an upfront cash payment of $15 million and will be eligible to receive success based development, regulatory and sales milestone payments by Takeda. The first $110 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. We will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

Reimbursement of R&D Costs

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D costs. Our policy is to account for the reimbursement payments by our collaboration partners as reductions to R&D expense.

The following table summarizes the reductions to R&D expenses related to the reimbursement payments:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2016	2015	2016	2015
Mylan	$ 25,971	$ 11,610	$ 57,144	$ 15,742
Alfa Wassermann	2,601	367	3,786	789
SciClone	98	—	98	—
R-Pharm	12	277	25	277
Total reduction to R&D expense	$ 28,682	$ 12,254	$ 61,053	$ 16,808

4. Available-for-Sale Securities and Fair Value Measurements

Our available-for-sale securities include:

	Fair Value Hierarchy	Estimated Fair Value	
(In thousands)	Level	June 30, 2016	December 31, 2015
U.S. government securities	Level 1	$ 52,227	$ 47,043
U.S. government agency securities	Level 2	44,381	31,465
Corporate notes	Level 2	24,173	19,089
Commercial paper	Level 2	91,927	4,990
Marketable securities (including commercial paper classified as cash equivalents)		212,708	102,587
Money market funds	Level 1	71,273	69,126
Total		$ 283,981	$ 171,713

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. The fair value of our marketable securities classified within Level 2 is based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. Net unrealized gains and losses were $0.2 million at June 30, 2016 and immaterial at December 31, 2015.

At June 30, 2016, all of the marketable securities had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately eight months. There were no transfers between Level 1 and Level 2 during the periods presented and there have been no changes to our valuation techniques during the three and six months ended June 30, 2016.

We do not intend to sell the investments that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at June 30, 2016 were temporary in nature. All marketable securities with unrealized losses at June 30, 2016 have been in a loss position for less than twelve months.

At June 30, 2016, our accumulated other comprehensive income (loss) on our condensed consolidated balance sheets consisted of net unrealized gains on available-for-sale investments. During the three and six months ended June 30, 2016, we did not sell any of our marketable securities. Restricted cash pertained to certain lease agreements and letters of credit where we have pledged cash and cash equivalents as collateral.

5. Inventories

Inventory consists of the following:

(In thousands)	June 30, 2016	December 31, 2015
Raw materials	$ 5,811	$ 6,869
Work-in-process	1,838	—
Finished goods	2,161	3,136
Total inventories	$ 9,810	$ 10,005

6. Share-Based Compensation

Share-Based Compensation Expense Allocation

The allocation of share-based compensation expense included in the condensed consolidated statements of operations was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2016	2015	2016	2015
Research and development	$ 4,959	$ 6,817	$ 10,119	$ 14,299
Selling, general and administrative	4,945	7,845	11,115	15,989
Total share-based compensation expense	$ 9,904	$ 14,662	$ 21,234	$ 30,288

Total share-based compensation expense capitalized to inventory was not material for any of the periods presented.

Performance-Contingent Awards

In the first quarter of 2016, the Compensation Committee of the Company's Board of Directors ("Compensation Committee") approved the grant of 1,575,000 performance-contingent restricted share awards ("RSAs") and 135,000 performance contingent restricted share units ("RSUs") to senior management. These grants have dual triggers of vesting based upon the achievement of certain performance conditions over a five-year timeframe from 2016 to 2020 and continued employment, both of which must be satisfied in order for the awards to vest.

Expense associated with these awards would be recognized during the years 2016 to 2020 depending on the probability of meeting the performance conditions. Compensation expense relating to awards subject to performance conditions is recognized if it is considered probable that the performance goals will be achieved. The probability of achievement will be reassessed at each reporting period.

In August 2016, the Compensation Committee determined not to award credit for a performance condition that occurred in the second quarter of 2016, which for accounting purposes is treated as a modification of the vesting conditions of all outstanding awards. As a result of the modification, the vesting of the first tranche of the awards changed from probable of achievement to improbable. The vesting of the second and third tranches of the awards is still considered improbable of achievement. As a result of the modification, there is a new measurement date for the second and third tranches of the awards as of the modification date. While the total number of shares under the award did not change, the remeasurement of the awards results in a higher potential compensation charge for the awards because our share price had increased since the original measurement date. The revised maximum potential expense associated with the awards could be up to approximately $38.9 million (allocated as $16.7 million for research and development expense and $22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved. In the second quarter of 2016, we recognized $0.7 million in share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first tranche of these awards were considered to be probable of vesting. As of June 30, 2016, we determined that the remaining second and third tranches were improbable of vesting and, as a result, no compensation expense related to these tranches has been recognized for the quarter.

7. Income Taxes

The income tax provision was $36,000 and $0.7 million for the three and six months ended June 30, 2016, respectively, although we incurred operating losses on a consolidated basis. The provision for income tax was primarily due to uncertain tax positions taken with respect to transfer pricing. No provision for income taxes has been recognized on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested.

We follow the accounting guidance related to accounting for income taxes which requires that a company reduce its deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some portion or all of its deferred tax assets will not be realized. At June 30, 2016, our deferred tax assets were offset in full by a valuation allowance.

We record liabilities related to uncertain tax positions in accordance with the income tax guidance which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Resolution of one or more of these uncertain tax positions in any period may have a material impact on the results of operations for that period. We include any applicable interest and penalties within the provision for income taxes in the condensed consolidated statements of operations.

The difference between the Irish statutory rate and our effective tax rate is primarily due to the valuation allowance on deferred tax assets and the liabilities recorded for the uncertain tax position related to transfer pricing and tax credits.

Our future income tax expense may be affected by such factors as changes in tax laws, our business, regulations, tax rates, interpretation of existing laws or regulations, the impact of accounting for share-based compensation, the impact of accounting for business combinations, our international organization, shifts in the amount of income before tax earned in the U.S. as compared with other regions in the world, and changes in overall levels of income before tax.

8. Shareholders' Equity

Ordinary Shares Issuance under At-the-Market Agreement

Pursuant to a sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), we may issue and sell up to $50 million of our ordinary shares pursuant to an at-the-market offering program ("ATM Agreement"), under our shelf registration statement on Form S-3 effective in July 2015. Under the ATM Agreement, we pay Cantor Fitzgerald a commission rate of up to 3.0% of the gross proceeds from the sale of our ordinary shares.

We engaged in sales of our ordinary shares under the ATM Agreement from March 17, 2016 to April 8, 2016. During this period, we sold approximately 770,000 shares at an average market price of $19.53 per share, resulting in aggregate net proceeds after offering costs of approximately $14.3 million. For the three and six months ended June 30, 2016, we sold approximately 490,000 and 770,000 shares, respectively.

Public Offering of Ordinary Shares

On May 4, 2016, we closed the sale of an aggregate of 5,479,750 of our ordinary shares, $0.00001 par value, at a public offering price of $21.00 per share. The shares were issued pursuant to a prospectus supplement filed with the SEC on April 28, 2016, in connection with a takedown from our shelf registration statement on Form S-3. We received net offering proceeds of approximately $107.9 million after deducting the underwriting discount and estimated offering expenses.

9. Commitments and Contingencies

Guarantees and Indemnifications

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of June 30, 2016.

10. Subsequent Events

Takeda Collaborative Arrangement

The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

You should read the following discussion in conjunction with our condensed financial statements (unaudited) and related notes included elsewhere in this report. This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), as amended, and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, that involve risks and uncertainties. All statements in this report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives are forward-looking statements. The words "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "intend," "may," "mission," "opportunities," "plan," "potential," "predict," "project," "pursue," "seek," "should," "target," "will," "would," and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our current views with respect to future events or our future financial performance, are based on assumptions, and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2015. Our forward-looking statements in this report are based on current expectations and we do not assume any obligation to update any forward-looking statements for any reason, even if new information becomes available in the future.

Management Overview

Theravance Biopharma, Inc. ("Theravance Biopharma") is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness.

Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist ("LAMA") being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease ("COPD"). Our neprilysin ("NEP") inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinases ("JAK") inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") (known as Theravance, Inc. prior to January 7, 2016) relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

Program Highlights

VIBATIV® (telavancin)

VIBATIV is a bactericidal, once-daily injectable antibiotic to treat patients with serious, life-threatening infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including methicillin-resistant ("MRSA") strains. VIBATIV is approved in the U.S. for the treatment of adult patients with complicated skin and skin structure infections ("cSSSI") caused by susceptible Gram-positive bacteria and for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia ("HABP"/ "VABP") caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. VIBATIV is indicated in the European Union for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. VIBATIV is also indicated in Canada and Russia for complicated skin and skin structure infections and HABP and VABP caused by Gram-positive bacteria, including MRSA.

Commercial Program Expansion

In 2014 and early 2015, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a limited number of targeted geographic territories across the country. In the second quarter of 2015, we announced our intention to expand our sales force to 50 representatives with the goal of further strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market. We achieved our goal of hiring and training additional sales representatives by the end of the third quarter of 2015, and the newly expanded field force was fully deployed by the beginning of the fourth quarter of 2015.

We plan to market VIBATIV outside the U.S. through a network of partners. To date, we have secured partners for VIBATIV in the following geographies—Canada, Middle East, North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen Group ("Clinigen") reached a mutual decision that Clinigen will return commercial rights to market and distribute VIBATIV in the European Union to Theravance Biopharma. Both companies are collaborating to transition the EU-focused commercial rights and activities for VIBATIV to ensure the product remains accessible to physicians and patients. Theravance Biopharma is in discussion with potential collaborators with the goal of establishing a new strategic commercial partnership in the EU.

Supplemental New Drug Application (sNDA) for Concurrent Staphylococcus aureus Bacteremia

In May 2016, we announced approval of our sNDA by the Food and Drug Administration ("FDA") allowing for the addition of new clinical data to the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. The sNDA submission was based on the combined data from our previously conducted pivotal trials of VIBATIV in its two approved indications—cSSSI (ATLAS I and ATLAS II) and HABP/VABP (ATTAIN I and ATTAIN II). The trials were large, multi-center, multi-national, double-blind, randomized Phase 3 clinical studies enrolling and treating 3,370 adult patients, including a portion of patients with concurrent bacteremia. Importantly, these studies involved two of the largest cohorts of patients ever studied in these diseases and included one of the largest cohorts of patients with MRSA infections studied to date. Separately, we are conducting a Phase 3 registrational study in patients with *Staphylococcus aureus* bacteremia.

Phase 3 Registrational Study in Staphylococcus aureus Bacteremia

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multi-center, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy. We expect to complete the study in 2018.

Telavancin Observational Use Registry ("TOUR")

Initiated in February 2015, the 1,000-patient TOUR observational use registry study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

Long-Acting Muscarinic Antagonist—Revefenacin (TD-4208)

Revefenacin is an investigational long acting muscarinic antagonist ("LAMA") in development for the treatment of COPD. We believe that revefenacin may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates there is an enduring population of COPD patients in the U.S. that either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. Revefenacin has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of revefenacin, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler products.

Mylan Collaboration

In January 2015, Mylan Ireland Limited ("Mylan") and we established a strategic collaboration for the development and, subject to regulatory approval, commercialization of revefenacin. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our revefenacin development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 development program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside revefenacin.

Under the terms of the Mylan Development and Commercialization Agreement (the "Mylan Agreement"), Mylan and we will co-develop nebulized revefenacin for COPD and other respiratory diseases. We are leading the U.S. Phase 3 development program and Mylan is responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (excluding China), Mylan will be responsible for development and commercialization and will pay us a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens. Although China is not included in the ex-U.S. territory, Mylan has a right of first negotiation with respect to the development and commercialization of nebulized revefenacin in China.

Under the Mylan Agreement, Mylan paid us an initial payment of $15.0 million in cash in the second quarter of 2015. Also, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., the indirect parent corporation of Mylan, made a $30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in early February 2015 in a private placement transaction at a price of approximately $18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. As of December 31, 2015, we are eligible to receive from Mylan potential development and sales milestone payments totaling $220.0 million in the aggregate, with $175.0 million associated with revefenacin monotherapy and $45.0 million for future potential combination products. In February 2016, we earned a $15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. We do not anticipate earning any new milestone payments from Mylan for the remainder of 2016.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler ("MDI"/"DPI"), while Mylan has certain rights of first negotiation with respect to our development and commercialization of revefenacin delivered other than via a nebulized inhalation product.

Phase 3 Study in COPD

In September 2015, we announced, with our partner Mylan, the initiation of the Phase 3 development program for revefenacin for the treatment of COPD. The Phase 3 development program, designed to support the registration of the product in the U.S., includes two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies will examine 2 doses (88 mcg and 175 mcg) of revefenacin inhalation solution administered once-daily via nebulizer in patients with moderate to severe COPD. The Phase 3 efficacy studies are replicate, randomized, double-blind, placebo-controlled, parallel-group trials designed to provide pivotal efficacy and safety data for once-daily revefenacin over a dosing period of 12 weeks, with a primary endpoint of trough forced expiratory volume in one second (FEV1) on day 85. The Phase 3 safety study is an open-label, active comparator study of 12 months duration. Together, the three studies will enroll approximately 2,300 patients. In February 2016, we announced the achievement of 50% enrollment in all three of the Phase 3 clinical studies for revefenacin. The achievement of 50% enrollment in the twelve-month safety study triggered a $15.0 million milestone payment to Theravance Biopharma by Mylan. In June 2016, we completed enrollment for all three studies. We expect to complete the efficacy studies early-fourth quarter of 2016, and the twelve-month safety study in 2017. If the Phase 3 program is successful, our goal would be to submit a regulatory filing in the U.S. in late-2017.

Oral Peripherally-Acting Mu Opioid Receptor Antagonist—Axelopran (TD-1211)

OIC Program

Axelopran is an investigational, once-daily, oral peripherally-active mu opioid receptor antagonist for opioid- induced constipation ("OIC"). The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3 registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

Fixed Dose Combination

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin® (oxycodone) and axelopran after oral administration as a fixed dose combination ("FDC") relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

Velusetrag

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. ("Alfa Wassermann") in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive top-line results from the initial Phase 2 proof-of-concept study under this partnership, which evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag, were announced in April 2014. In March 2015, we initiated a Phase 2b study of velusetrag for the treatment of patients with gastroparesis and other gastrointestinal motility disorders. The 200-patient study is a multi-center, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic or idiopathic gastroparesis. The twelve-week study will test three doses: 5, 15, and 30 mg administered once-daily. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale, a daily patient-reported outcome measure. We currently expect to complete the Phase 2b study in 2017. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study is, funded by Alfa Wassermann.

NS5A Inhibitor—TD-6450

TD-6450 is an internally discovered multivalent NS5A inhibitor designed to have improved antiviral activity against GT-1 resistance-associated variants resistant to first generation NS5A inhibitors. TD-6450 has successfully completed Phase 1 studies in both healthy volunteers and hepatitis C virus ("HCV") patients. In September 2015, we entered into a licensing agreement with Trek Therapeutics, PBC ("TREKtx") (the "TREKtx Agreement") granting TREKtx an exclusive worldwide license for the development, manufacturing, use, marketing and sale of TD-6450 as a component in combination HCV products (the "HCV Products"). Pursuant to the TREKtx Agreement, we received an upfront payment of $8.0 million in the form of TREKtx's Series A preferred stock and will be eligible to receive future royalties based on net sales of the HCV Products. In October 2015, TREKtx and we announced that TREKtx had initiated a Phase 2a clinical trial to evaluate faldaprevir ("FDV"), an HCV protease inhibitor, combined with TD-6450 and ribavirin ("RBV") in patients infected with HCV genotype 4. In June 2016, TREKtx announced interim results from its Phase 2a study evaluating FDV plus TD-6450 and RBV in patients will HCV genotype 4, as well as, the initiation of a second Phase 2a study of FDV and TD-6450, with and without RBV in patients with HCV genotype 1.

Neprilysin (NEP) Inhibitor Program

Neprilysin ("NEP") is an enzyme that degrades natriuretic peptides. These peptides play a protective role in controlling blood pressure and preventing cardiovascular tissue remodeling. Inhibiting NEP may result in clinical benefit for patients, including diuresis, control of blood pressure, and reversing maladaptive changes in the heart and vascular tissue in patients with congestive heart failure. Our primary objective is to develop a NEP inhibitor that could be used across a broad population of patients with cardiovascular and renal diseases, including acute and chronic heart failure and chronic kidney disease, including diabetic nephropathy. We intend to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Specifically, compounds that are non-renally cleared, dosed once-daily, dosed alone or in combination with other medicines and that may be dosed orally or intravenously.

Phase 1 Single Ascending Dose (SAD) Study

In March 2016, we completed a Phase 1 clinical study of our most advanced NEP inhibitor compound, TD-0714. The Phase 1 trial was a randomized, double-blind, placebo-controlled, single ascending dose study in healthy volunteers. The study was designed to assess the safety, tolerability and pharmacokinetics of TD-0714, as well as measure biomarker evidence of target engagement and the amount of the drug that is eliminated via the kidneys. Results from the SAD study of TD-0714 demonstrate that the compound achieved maximal and sustained levels of target engagement for 24 hours after a single-dose, supporting the drug's potential for once-daily dosing. Target engagement was measured by dose-related increases in the levels of cyclic GMP (cGMP, a well-precedented biomarker of NEP engagement). TD-0714 also demonstrated very low levels of renal elimination, as evidenced by intravenous microtracer testing technology, and a favorable safety and tolerability profile. These results met the Company's target product profile and provide confidence for future efficacy studies of TD-0714 in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function. Theravance Biopharma is now conducting a Phase 1 multiple ascending dose ("MAD") study of TD-0714 that is designed to supplement the findings of the SAD study and support the ongoing clinical development of the molecule. We expect to complete the MAD study in the second half of 2016.

Gastrointestinal (GI)-Targeted Pan-Janus Kinase (JAK) Inhibitor Program

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis, myelofibrosis and psoriasis. However, these products are known to have side effects based on their systemic exposure. This mechanism has previously demonstrated therapeutic benefit for patients with ulcerative colitis. Currently available treatments for ulcerative colitis have systemic safety liabilities and limited efficacy. Our goal is to develop an orally administered GI-targeted pan-JAK inhibitor designed to distribute adequately and predominantly to the tissues of the GI tract, treating inflammation in those tissues while minimizing systemic exposure. We are focused on utilizing targeted JAK inhibitors for potential treatment of inflammatory intestinal disease including ulcerative colitis.

Phase 1 Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) Studies

In June 2016, we completed a Phase 1 clinical study of TD-1473, an internally-discovered JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes. The primary objective of the study was to evaluate the safety and tolerability of single ascending and multiple ascending doses of TD-1473 in healthy volunteers. A key secondary objective of the trial was to characterize the pharmacokinetics of TD-1473, to determine the amount of TD-1473 that entered systemic circulation following oral administration. Data from the study demonstrated TD-1473 to be generally well tolerated. Study results also demonstrated that systemic exposures of TD-1473 were low relative to that reported for tofacitinib, a JAK inhibitor currently in development for ulcerative colitis. At steady state, the plasma exposures of TD-1473 at daily doses of 30 mg and 100 mg were approximately 75-fold and 15-fold lower, respectively, as compared to the plasma exposure of tofacitinib at twice daily doses of 10 mg.

Furthermore, subjects exhibited high stool concentrations of TD-1473, which were comparable to concentrations associated with efficacy in preclinical colitis models. Preclinical studies also demonstrated penetration of TD-1473 into the intestinal wall and membrane. The data generated from the study met our target pharmacokinetic profile and support progression into a Phase 1b trial in ulcerative colitis patients later this year, with data expected in 2017.

Previously announced findings from a preclinical model of colitis evaluating TD-1473 and tofacitinib demonstrated that both compounds significantly reduced disease activity scores. However, at doses providing similar preclinical efficacy, the systemic exposure of TD-1473 was much lower than that of tofacitinib and TD-1473 did not reduce systemic immune cell counts, in contrast to tofacitinib. Based on these preclinical findings, we believe that TD-1473 represents a potential breakthrough approach to treating ulcerative colitis without the risk generally associated with systemically active therapies.

Selective 5-HT4 Agonist (TD-8954)

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the "Takeda Agreement") with Millennium Pharmaceuticals, Inc., a Delaware corporation ("Millennium"), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Prior to the Takeda Agreement, the Company has developed TD-8954 for potential use in the treatment of gastrointestinal motility disorders, including short-term intravenous use for enteral feeding intolerance ("EFI") to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received U.S. Food and Drug Administration ("FDA") Fast Track Designation. Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE: 4502), a publicly-traded Japanese corporation listed on the Tokyo Stock Exchange (collectively with Millennium, "Takeda"). Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. We will receive an upfront cash payment of $15 million and will be eligible to receive success based development, regulatory and sales milestone payments by Takeda. The first $110 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. We will also be eligible to receive a tiered royalty on worldwide net sales by Takeda at percentage royalty rates ranging from low double-digits to mid-teens.

The transactions contemplated by the Takeda Agreement closed in the third quarter, following the expiration of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). Upon closing and the subsequent transfer of the license and technical know-how, we have the right to receive an upfront payment of $15 million.

Other Programs

Economic Interest in GSK-Partnered Respiratory Programs

We are entitled to receive an 85% economic interest in any future payments that may be made by GSK (pursuant to its agreements with Innoviva) relating to certain of the respiratory programs that Innoviva partnered with GSK and assigned to Theravance Respiratory Company, LLC ("TRC") in connection with the Spin-Off (the "GSK-Partnered Respiratory Programs") consisting primarily of the Closed Triple program and the Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program, each of which are described in more detail below. We are entitled to this economic interest through our equity ownership in TRC. Our economic interest will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Closed Triple and the MABA program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

"Closed Triple" or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)

The Closed Triple program seeks to provide the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device administered once-daily. If the Closed Triple is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties are upward-tiering from 6.5% to 10%. Previously, Innoviva and GSK announced the initiation of two global pivotal Phase 3 studies of the Closed Triple. The IMPACT study, which will enroll approximately 10,000 COPD patients, was initiated in July 2014. The IMPACT study will assess whether the Closed Triple can reduce the rate of moderate and severe exacerbations compared with two approved once-daily COPD treatments, RELVAR® ELLIPTA®/BREO® ELLIPTA® (FF/VI), an ICS/LABA combination, and ANORO® ELLIPTA® (UMEC/VI), a LAMA/LABA combination. The IMPACT study is ongoing and is expected to read out in 2017. The FULFIL study, which enrolled approximately 1,800 COPD patients was initiated in February 2015. In June 2016, GSK and Innoviva disclosed positive top-line results from the FULFIL study, in which data demonstrated superiority of the Closed Triple as compared to twice-daily SYMBICORT® TURBOHALER® (budesonide/formoterol) in improving lung function and health-related quality of life in COPD patients. Also in June 2016, GSK and Innoviva announced plans to accelerate the timeline for filing the New Drug Application (NDA) in the U.S. for the Closed Triple from first half 2018 to end of 2016. In June 2016, GSK and Innoviva confirmed previously communicated plans to file an EU regulatory submission by the end of 2016.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 ('081), also known as batefenterol, is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity that was discovered by us when we were part of Innoviva. Innoviva and GSK are conducting two Phase 2 clinical trials for batefenterol and batefenterol/FF, which will enroll approximately 380 patients with COPD.

If a single-agent MABA medicine containing ‘081 is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties range between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing ‘081 is commercialized only as a combination product, such as ‘081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing ‘081 is successfully developed and commercialized in multiple regions of the world, GSK will pay TRC contingent milestone payments of up to $125.0 million for a single-agent medicine and up to $250.0 million for both a single-agent and a combination medicine, and in each case we would be entitled to receive an 85% economic interest in any such payments.

Theravance Respiratory Company, LLC

Prior to the June 1, 2014 separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma (the “Spin-Off”), Innoviva assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC is the mechanism by which we are entitled to the 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC. The drug programs assigned to TRC include the Closed Triple and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (“ICS”), as well as any other product or combination of products that may be discovered and developed in the future under these GSK agreements.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Other than the below, there have been no material changes to the critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2015.

In the first quarter of 2016, the Compensation Committee of the Company’s Board of Directors (“Compensation Committee”) approved the grant of 1,575,000 performance-contingent restricted share awards (“RSAs”) and 135,000 performance contingent restricted share units (“RSUs”) to senior management. These grants have dual triggers of vesting based upon the achievement of certain performance conditions over a five-year timeframe from 2016 to 2020 and continued employment, both of which must be satisfied in order for the awards to vest.

Expense associated with these awards would be recognized during the years 2016 to 2020 depending on the probability of meeting the performance conditions. Compensation expense relating to awards subject to performance conditions is recognized if it is considered probable that the performance goals will be achieved. The probability of achievement will be reassessed at each reporting period.

In August 2016, the Compensation Committee determined not to award credit for a performance condition that occurred in the second quarter of 2016, which for accounting purposes is treated as a modification of the vesting conditions of all outstanding awards. As a result of the modification, the vesting of the first tranche of the awards changed from probable of achievement to improbable. The vesting of the second and third tranches of the awards is still considered improbable of achievement. As a result of the modification, there is a new measurement date for the second and third tranches of the awards as of the modification date. While the total number of shares under the award did not change, the remeasurement of the awards results in a higher potential compensation charge for the awards because our share price had increased since the original measurement date. The revised maximum potential expense associated with the awards could be up to approximately $38.9 million (allocated as $16.7 million for research and development expense and $22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved. In the second quarter of 2016, we recognized $0.7 million in share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first tranche of these awards were considered to be probable of vesting. As of June 30, 2016, we determined that the remaining second and third tranches were improbable of vesting and, as a result, no compensation expense related to these tranches has been recognized for the quarter.

Results of Operations

Product Sales and Revenue from Collaborative Arrangements

Product sales and revenue from collaborative arrangements, as compared to the comparable period in the prior year, were as follows:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(In thousands)	2016	2015	$	%	2016	2015	$	%
Product sales	$ 5,359	$ 2,124	$ 3,235	152%	$ 8,670	$ 3,404	$ 5,266	155%
Revenue from collaborative arrangements	112	5,010	(4,898)	(98)	15,211	24,131	(8,920)	(37)
Total revenue	$ 5,471	$ 7,134	$ (1,663)	(23)%	$ 23,881	$ 27,535	$ (3,654)	(13)%

Revenue from product sales increased by $3.2 million and $5.3 million for the three months and six months ended June 30, 2016, respectively, compared to the same periods in 2015. Both increases resulted primarily from the expansion of our VIBATIV sales infrastructure that was completed in the fourth quarter of 2015.

Revenue from collaborative arrangements decreased by $4.9 million for the three months ended June 30, 2016 compared to the same period in 2015. The decrease was attributed to a $2.95 million upfront payment from a new collaboration arrangement with SciClone Pharmaceutical International Holding Ltd. (“SciClone”) and a $2.0 million VIBATIV development milestone payment from R-Pharm both recorded in the second quarter of 2015.

Revenue from collaborative arrangements decreased by $8.9 million for the six months ended June 30, 2016 compared to the same period in 2015. For the six months ended June 30, 2016, we recognized a $15.0 million milestone payment from Mylan for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Comparatively for the same period in 2015, we recognized $19.1 million of upfront payments related to the delivery of the license and technological know-how to Mylan and $4.95 million related to the SciClone upfront and R-Pharm milestone payments described above.

Cost of Goods Sold

Cost of goods sold, as compared to the comparable period in the prior year, was as follows:

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(In thousands)	2016	2015	$	%	2016	2015	$	%
Cost of goods sold	$ 638	$ 505	$ 133	26%	$ 1,416	$ 875	$ 541	62%

Costs of goods sold increased by by $0.1 million for the three months ended June 30, 2016 compared to the same period in 2015. The increase was due to $0.2 million in royalty payments related to the increase in VIBATIV sales and a $0.1 million charge for the write-down of short-dated VIBATIV inventory. These increases were partially offset by a $0.2 million decrease in cost of goods sold due to the sale of VIBATIV vials that were previously written off.

Costs of goods sold increased by $0.5 million for the six months ended June 30, 2016 compared to the same period in 2015. The increase was primarily attributed to the increase in the sales of VIBATIV, including a $0.2 million increase in royalty payments.

Research and Development

Our research and development (“R&D”) expenses consist primarily of employee-related costs, external costs, and various allocable expenses. We budget total R&D expenses on an internal department level basis, and we manage and report our R&D activities across the following four cost categories:

1) Employee-related costs, which include salaries, wages and benefits;

2) Share-based compensation, which includes expenses associated with our equity plans;

3) External-related costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees; and

4) Facilities and other, which include laboratory and office supplies, depreciation and other allocated expenses, which include general and administrative support functions, insurance and general supplies.

The following table summarizes our R&D expenses incurred, net of reimbursements from collaboration partners, during the periods presented:

(In thousands)	Three Months Ended June 30, 2016	2015	Change $	%	Six Months Ended June 30, 2016	2015	Change $	%
Employee-related	$ 8,881	$ 10,016	$ (1,135)	(11)%	$ 19,400	$ 22,965	$ (3,565)	(16)%
Share-based compensation	4,959	6,817	(1,858)	(27)	10,119	14,299	(4,180)	(29)
External-related	11,510	6,879	4,631	67	24,613	15,815	8,798	56
Facilities, depreciation and other allocated	6,719	6,665	54	1	13,616	13,317	299	2
Total research and development expenses	$ 32,069	$ 30,377	$ 1,692	6%	$ 67,748	$ 66,396	$ 1,352	2%

R&D expenses increased by $1.7 million for the three months ended June 30, 2016 compared to the same period in 2015. The increase was attributed to a $4.6 million increase in external-related costs that was primarily driven by costs associated with the progression of our priority programs. This increase was offset by decreases in our employee-related and share-based compensation expenses of $1.1 million and $1.9 million, respectively, primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

R&D expenses increased by $1.4 million for the six months ended June 30, 2016 compared to the same period in 2015. The increase was attributed to an $8.8 million increase in external-related costs that was primarily driven by costs associated with the progression of our priority programs. This increase was offset by decreases in our employee-related and share-based compensation expenses of $3.6 million and $4.2 million, respectively, primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

Under certain of our collaborative arrangements we receive partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of $28.7 million and $61.1 million for three and six months ended June 30, 2016, respectively, and $12.3 million and $16.8 million for the three and six months ended June 30, 2015, respectively. The increases were primarily due to expense reimbursements received from Mylan related to the progression of our revefenacin program.

Selling, General and Administrative Expenses

Selling, general and administrative expenses, as compared to the comparable period in the prior year, were as follows:

(In thousands)	Three Months Ended June 30, 2016	2015	Change $	%	Six Months Ended June 30, 2016	2015	Change $	%
Selling, general and administrative	$ 20,261	$ 21,545	$ (1,284)	(6)%	$ 43,857	$ 43,293	$ 564	1%

Selling, general and administrative expenses decreased by $1.3 million for three months ended June 30, 2016 compared to the same period in 2015. The $1.3 million decrease was primarily due to a $2.9 million decrease in share-based compensation expense primarily due to costs incurred in the second quarter of 2015 associated with long-term retention and incentive awards granted to certain employees in 2012 and 2011. The decrease was partially offset by a $1.5 million increase related to the expansion of our internal sales and marketing organization supporting VIBATIV.

Selling, general and administrative expenses increased by $0.6 million for six months ended June 30, 2016 compared to the same period in 2015. The $0.6 million increase was primarily attributed to a $4.6 million increase related to the expansion of our internal sales and marketing organization supporting VIBATIV and a $0.8 million increase related to consulting services. These increases were partially offset by a $4.9 million decrease in share-based compensation expense primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2012 and 2011.

Provision for Income Taxes

(In thousands)	Three Months Ended June 30, 2016	2015	Change $	Change %	Six Months Ended June 30, 2016	2015	Change $	Change %
Provision for income taxes	$ 36	$ 2,514	$ (2,478)	(99)%	$ 730	$ 7,463	$ (6,733)	(90)%

Our effective tax rate for the six months ended June 30, 2016 was approximately (1.0)% which was consistent with the effective tax rate for the year ended December 31, 2015. The provision for income taxes for all periods presented reflect primarily the U.S. federal taxes associated with the intercompany services that the Company's U.S. subsidiary performs for the Company. Although we incurred operating losses on a consolidated basis, the provision for income taxes was due to the uncertain tax positions taken with respect to transfer pricing. The provision for income taxes decreased to $36,000 and $0.7 million for the three and six months ended June 30, 2016, respectively, compared to $2.5 million and $7.4 million for the respective periods in 2015 due to changes in our transfer pricing.

Liquidity and Capital Resources

We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV. In particular, to the extent we advance our product candidates into and through later-stage clinical studies without a partner, we will incur substantial expenses. In 2015, we made additional investments in telavancin, our approved antibiotic. For example, in February 2015, we initiated a Phase 3 registrational study for bacteremia and a patient registry study. In addition, we increased the number of VIBATIV sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies.

Adequacy of cash resources to meet future needs

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months based on current operating plans and financial forecasts.

If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements.

In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective (the "Form S-3"). Up to $50.0 million of the maximum aggregate offering price under the registration statement may be issued and sold pursuant to an at-the-market offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. ("ATM Agreement"), which acts as our sales agent and underwriter under the agreement.

In October 2015, we entered into an Ordinary Share Purchase Agreement (the "Purchase Agreement") with funds managed by Woodford Investment Management LLP for the registered direct offering of an aggregate of 3,859,649 of our ordinary shares at a purchase price of $14.25 per share. The shares were issued pursuant to a prospectus supplement filed with the Securities and Exchange Commission ("SEC") on October 26, 2015, in connection with a takedown from our shelf registration statement on Form S-3. The closing of the transaction occurred on October 29, 2015 and the net offering proceeds were approximately $53.0 million.

On March 17, 2016, GSK purchased 1,301,015 of our unregistered ordinary shares at a price of $17.70 per share pursuant to an Ordinary Share Purchase Agreement between the Company and GSK, dated as of March 14, 2016. The aggregate gross proceeds of the purchase were approximately $23.0 million and no underwriting discounts or commissions were paid in this transaction.

We commenced selling ordinary shares under the ATM Agreement from March 17, 2016. As of April 8, 2016, we sold approximately 770,000 of our ordinary shares at an average market price of $19.53 per share, resulting in aggregate net proceeds after offering costs of approximately $14.3 million. As favorable financing opportunities arise, we may seek to continue to raise capital under the ATM Agreement or through other debt or equity offerings to fund our operations. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

On May 4, 2016, we closed the sale of an aggregate of 5,479,750 of our ordinary shares at a public offering price of $21.00 per share. The shares were issued pursuant to a prospectus supplement filed with the SEC on April 28, 2016, in connection with a takedown from our shelf registration statement on Form S-3. We received net offering proceeds of approximately $107.9 million after deducting the underwriting discount and estimated offering expenses.

Without adequate financial resources to fund our operations as presently conducted, we may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may also have to sequence pre-clinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. In addition, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities.

Cash Flows

Cash flows, as compared to the comparable period in the prior year, were as follows:

	Six Months Ended June 30,		
(In thousands)	**2016**	**2015**	**Change**
Net cash used in operating activities	$ (58,444)	$ (103,128)	$ 44,684
Net cash (used in) provided by investing activities	(52,190)	83,453	(135,643)
Net cash provided by financing activities	146,290	27,550	118,740

Cash flows used in operating activities

Net cash used in operating activities was $58.4 million for the six months ended June 30, 2016, consisting primarily of net loss of $89.4 million, adjusted for non-cash items such as $21.2 million for share-based compensation expense, and $8.4 million of net cash inflow related to changes in operating assets and liabilities. The $8.4 million net cash inflow related to changes in operating assets and liabilities was primarily attributable to $9.6 million in net tax refunds during the six months period ended June 30, 2016.

Net cash used in operating activities was $103.1 million for the comparable period in 2015, consisting primarily of net loss of $90.1 million, adjusted for non-cash items such as $30.3 million for share-based compensation expense, and $44.8 million of net cash outflow related to changes in operating assets and liabilities. The $44.8 million net cash outflow related to changes in operating assets and liabilities was primarily attributable to an increase in receivables from collaborative arrangements of $23.6 million and increases in accounts payable and accrued expenses of $17.0 million for the six months ended June 30, 2015.

Cash flows (used in) provided by investing activities

Net cash used in investing activities was $52.2 million for the six months ended June 30, 2016, consisting of outflows related to net purchases and maturities of marketable securities of $50.9 million and by purchases of property and equipment of $1.3 million.

Net cash provided by investing activities was $83.5 million for the comparable period in 2015, consisting of inflows related to net purchases and maturities of marketable securities of $84.8 million and by purchases of property and equipment of $1.4 million.

Cash flows provided by financing activities

Net cash provided by financing activities was $146.3 million for the six months ended June 30, 2016, consisting primarily of $107.9 million related to the sale of ordinary shares through our public equity offering, $23.0 million related to the sale of ordinary shares to GSK, and $14.3 million through our at-the-market offering program.

Net cash provided by financing activities was $27.6 million for the comparable period in 2015, consisting primarily of the sales of ordinary shares to Mylan for total net proceeds of $25.8 million.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of June 30, 2016.

Off-Balance Sheet Arrangements

There have been no material changes in our off-balance sheet arrangements from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 11, 2016.

Contractual Obligations and Commercial Commitments

There have been no material changes in our contractual obligations and commercial commitments from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 11, 2016.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks as of June 30, 2016 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of June 30, 2016, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are 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 under the Exchange Act is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, 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.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance Biopharma have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

During the second quarter of 2016, we implemented a new enterprise resource planning ("ERP") system. The new ERP system was designed and implemented, in part, to enhance the overall system of internal controls over financial reporting through further automation and integration of business processes. In connection with the ERP implementation, we updated the processes that constitute our internal control over financial reporting, as necessary, to accommodate related changes to our accounting procedures and business processes.

Other than the ERP implementation, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the second quarter of the year ending December 31, 2016 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material litigation or other material legal proceedings.

ITEM 1A. RISK FACTORS

RISKS RELATING TO THE COMPANY

The risks described below and elsewhere in this Report and in our other public filings with the SEC are not the only risks facing the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.

First as part of Innoviva, Inc. (known as Theravance, Inc. prior to January 7, 2016), and since June 2, 2014 as Theravance Biopharma, we have been engaged in discovery and development of compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines, royalties on sales by our partners or from our interest in Theravance Respiratory Company, LLC ("TRC") to achieve profitability. During the six months ended June 30, 2016 and years ended December 31, 2015 and 2014, we recognized losses of $89.4 million, $182.2 million and $237.0 million, respectively, which are reflected in the Shareholders' Equity on our consolidated balance sheets. We reflect cumulative net loss incurred and retained after June 2, 2014, the effective date of the Spin-Off, as accumulated deficit on our consolidated balance sheets. We expect to continue to incur net losses at least over the next several years as we continue our drug discovery and development efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV® (telavancin). In particular, to the extent we advance our product candidates into and through later-stage clinical studies without a partner, we will incur substantial expenses. We are also making additional investments in telavancin, our antibiotic that has been approved for certain difficult-to-treat infections. For example, in February 2015 we initiated a Phase 3 registrational study of telavancin for bacteremia and a patient registry study. We are incurring all of the costs and expenses associated with the commercialization of VIBATIV in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expanded medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies. Our commitment of resources to VIBATIV, to the continued development of our existing product candidates and to our discovery programs will require significant additional funding. Our operating expenses also will increase if, among other things:

- our earlier stage potential products move into later-stage clinical development, which is generally more expensive than early stage development;
- additional preclinical product candidates are selected for clinical development;
- we pursue clinical development of our potential or current products in new indications;
- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products or businesses.

Other than revenues from sales of VIBATIV, our only approved medicine, and potential payments under collaboration agreements, we do not expect to generate sales revenues from our programs for the foreseeable future. Since we or our collaborators or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market and sell such products with desired margins, our expenses may continue to exceed any revenues we may receive.

In the absence of substantial licensing payments, contingent payments or other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from VIBATIV and product candidates in development that receive regulatory approval or other sources of revenues, we will continue to incur operating losses and will require additional capital to execute our business strategy. The likelihood of reaching, and time required to reach, and then to sustain, profitability are highly uncertain. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will ever be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

If additional capital is not available, we may have to curtail or cease operations or we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.

Based on our current operating plans and financial forecasts, we believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans or financial forecasts change, we may require or seek additional funding sooner in the form of public or private equity or equity-linked offerings, debt financings or additional collaborations and licensing arrangements. For example, if we choose to progress any of our product candidates into later-stage development on our own, our capital needs would increase substantially. We also are making significant investments in telavancin, our approved antibiotic, which increases our operating expenses. For example, in February 2015 we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, in 2015 we substantially increased the number of sales representatives and medical science liaisons supporting physician education on the proper usage of VIBATIV in the U.S. and at the end of 2015 we had approximately 50 sales representatives in the field.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next twelve months based on current operating plans and financial forecasts, we may need to raise additional capital in the future to, among other things:

- fund our discovery efforts and research and development programs;
- fund our commercialization strategies for VIBATIV;
- progress mid-to-late stage product candidates into later-stage development, if warranted;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our discovery efforts and research and development programs;
- continued scientific progress in these programs;
- the extent to which we encounter technical obstacles in our research and development programs;
- the outcome of potential licensing or partnering transactions, if any;
- competing technological developments;
- the extent of our proprietary patent position in telavancin and our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.

We may seek to raise additional capital or obtain future funding through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies, product candidates or territories, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. We may sequence pre-clinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. If we are unable to raise additional capital or obtain future funding in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery, development and commercialization efforts and exploiting other corporate opportunities. This would likely harm our business, prospects and financial condition and cause the price of our securities to fall.

We may seek to obtain future financing through the issuance of debt or equity, which may have an adverse effect on our shareholders or may otherwise adversely affect our business.

If we raise funds through the issuance of debt, convertible debt or equity, any debt securities or preferred shares issued will have rights, preferences and privileges senior to those of holders of our ordinary shares in the event of liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of ordinary shares. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of our current shareholders that do not participate in the issuance. For example, in connection with entering into a collaboration agreement with Mylan, Inc. ("Mylan") for the development and commercialization of a nebulized formulation of our long-acting muscarinic antagonist ("LAMA") revefenacin (TD-4208) in February 2015, Mylan made a $30.0 million equity investment in us by purchasing 1,585,790 newly issued ordinary shares, which issuance resulted in dilution of ownership to our shareholders. By way of further example, in October 2015, funds managed by Woodford Investment Management LLP (collectively, the "Woodford Funds") made a $55.0 million equity investment in us by purchasing 3,859,649 newly issued ordinary shares, and in March 2016, GSK made an approximately $23.0 million equity investment in us by purchasing 1,301,015 newly issued ordinary shares, which issuances resulted in dilution of ownership to our shareholders. In addition, if we seek to raise funds and this becomes known publicly, the market price of our shares could decline upon the expectation of dilution, regardless of whether dilution actually occurs. In July 2015, our shelf registration statement on Form S-3 for the potential offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our debt securities, ordinary shares, and/or warrants was declared effective. Up to $50.0 million of the maximum aggregate offering price of $250.0 million under the registration statement may be issued and sold pursuant to an at-the-market offering program for sales of our ordinary shares under a sales agreement with Cantor Fitzgerald & Co. ("Cantor"). In October 2015, we used approximately $55 million of the available financing capacity under the registration statement in the foregoing sale of ordinary shares to the Woodford Funds, in March and April of 2016, we used approximately $15 million of the available financing capacity under the registration statement pursuant to our at-the-market offering program for sales of approximately 770,000 ordinary shares under the foregoing sales agreement with Cantor, and in May of 2016, we used approximately $115 million of the available financing capacity under the registration statement pursuant to a public offering of 5,479,750 ordinary shares. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to develop and/or commercialize products or technologies that we would otherwise seek to develop and/or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of debt securities may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our share capital, or make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we will be unable to fully develop and commercialize all of our product candidates and our business will be adversely affected.

We have collaborations with a number of third parties including Mylan for the development and commercialization of a nebulized formulation of revefenacin (TD-4208), our LAMA compound, Alfa Wassermann S.p.A. ("Alfa Wassermann") for velusetrag, Takeda for the development and commercialization of a selective 5-HT4 receptor agonist (TD-8954) and other companies for regional development and commercialization of VIBATIV. Also, through our interest in TRC we may participate economically in Innoviva's collaborations with GSK with respect to the GSK-Partnered Respiratory Programs and we received non-marketable equity securities in connection with our September 2015 licensing agreement with Trek Therapeutics, PBC. Additional collaborations will likely be needed to fund later-stage development of certain programs that have not been licensed to a collaborator, such as our NEP inhibitor program and axelopran (TD-1211) for opioid-induced constipation and to commercialize the product candidates in these programs if approved by the necessary regulatory authorities. We may also seek collaboration arrangements with additional third parties to pursue the future commercialization of VIBATIV. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and

if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs or otherwise be unsuccessful in their efforts with respect to our products or product candidates. Our inability to successfully collaborate with third parties would increase our development costs and may cause us to choose not to continue development of certain product candidates, would limit the likelihood of successful commercialization of some of our product candidates and could cause the price of our securities to fall.

We do not control TRC and, in particular, have no control over or access to non-public information about the GSK-Partnered Respiratory Programs.

Innoviva has assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC (the "GSK Agreements"). Our equity interest covers various drug programs including the Closed Triple combination of fluticasone furoate (FF)/umeclidinium (UMEC)/vilanterol (VI) (ICS/LAMA/LABA) and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid ("ICS"), and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. Our economic interest does not include any payments by GSK associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. Innoviva controls TRC and, except for certain limited consent rights, we have no right to participate in the business and affairs of TRC. Innoviva has the exclusive right to appoint TRC's manager who, among other things, is responsible for the day-to-day management of the GSK-Partnered Respiratory Programs and exercises the rights relating to the GSK-Partnered Respiratory Programs. As a result, we have no rights to participate in, or access to non-public information about, the development and commercialization of the GSK-Partnered Respiratory Programs and no right to enforce rights under the GSK Agreements assigned to TRC. Moreover, we have many of the same risks with respect to our and TRC's dependence on GSK as we have with respect to our dependence on our own partners.

If the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to these programs, our business will be harmed, and the price of our securities could fall.

We have no access to confidential information regarding the progress of, or plans for, the GSK-Partnered Respiratory Programs, including the Closed Triple program and the MABA program, and we have little, if any, ability to influence the progress of those programs because our interest in these programs is only through our economic interest in TRC, which is controlled by Innoviva. However, if any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to such programs, our business will be harmed, and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- GSK deciding to delay or halt development of any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple, GSK961081 ('081), the lead compound in the MABA program ('081/FF);
- the U.S. Food and Drug Administration ("FDA") and/or other regulatory authorities determining that any of the studies under these programs do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs; or
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs.

VIBATIV may not be broadly accepted by physicians, patients, third-party payors, or the medical community in general, which would have a material, adverse effect on our business.

The commercial success of VIBATIV depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. VIBATIV may not be sufficiently accepted by these parties. VIBATIV competes with vancomycin (which accounts for a substantial majority of patient treatment days) and linezolid, both relatively inexpensive generic drugs that are manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. In addition, sales of a generic version of daptomycin could begin in 2016. If we are unable to demonstrate to physicians that, based on experience, clinical data, side effect profiles and other factors, VIBATIV is a preferred injectable treatment for treating the infections for which it is indicated, we may never generate significant revenue from VIBATIV. In that case we may in the future reassess the VIBATIV business and respond in a number of ways which could include, for example, reducing our investment in commercialization and development efforts or other actions, any of which could cause the price of our securities to fall. In addition, if we fail to meet expectations about our net sales of VIBATIV and our VIBATIV commercialization strategy, the price of our securities could fall. For example, we reduced our projected U.S. net sales target for VIBATIV for 2015 more than once.

The degree of market acceptance of VIBATIV, the rate of our VIBATIV sales and our ability to generate revenues through sales of VIBATIV depends on a number of factors, including, but not limited to:

- the experiences of physicians, patients and payors with the use of VIBATIV;
- the market price of VIBATIV relative to competing therapies;
- the timing, frequency and impact of price changes or changes to pricing programs;
- our customer mix;
- any adverse developments or perceived adverse developments with respect to Hospira, Inc. (now a subsidiary of Pfizer, Inc.) (“Hospira”) which may adversely impact our single source of supply for VIBATIV drug product;
- any developments with, or comments by, the FDA or other regulatory agencies with respect to the manufacture, use or sale of VIBATIV;
- our ability to complete our ongoing Phase 3 registrational study for use of telavancin in the treatment of patients with *Staphylococcus aureus* bacteremia, the timing of any such completion, and the results of this study;
- the advantages and disadvantages of VIBATIV compared to alternative therapies;
- our ability to educate the medical community about the appropriate circumstances for use of VIBATIV;
- the acceptance of VIBATIV onto formulary by hospitals and healthcare systems;
- our ability to attract, train and retain appropriate numbers of sales and marketing personnel in the U.S.;
- our ability to attract, train and retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;
- the effectiveness of sales personnel in obtaining access to and educating adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- the reimbursement policies of government and third-party payors, including the amount of chargebacks and government rebates.

We are developing the capability to market, sell and distribute VIBATIV in the U.S. without a partner and we may bear similar costs with respect to additional products in the future, which subjects us to certain risks.

We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure.

VIBATIV was returned by Astellas Pharma Inc. ("Astellas"), our former VIBATIV collaboration partner, in January 2012, and Astellas is entitled to a ten-year, 1% royalty on future net sales of VIBATIV. On August 14, 2013, we (at the time with Innoviva) announced the reintroduction of VIBATIV to the U.S. market with the commencement of shipments into the wholesaler channel and as of the end of 2015 we had approximately 50 VIBATIV sales representatives in the U.S. The risks of commercializing VIBATIV in the U.S. without a partner include:

- costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, including third- party vendor logistics and consultant support, which costs and expenses could, depending on the scope and method of the marketing effort, exceed any product revenue from VIBATIV for several years;
- our unproven ability to retain adequate numbers of effective sales and marketing personnel in the U.S.;
- our unproven ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;
- the unproven ability of sales personnel to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- bearing the full costs of further U.S. development of telavancin.

If we are not successful in maintaining an internal sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure, distribution capability and the ability to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations, we will have difficulty commercializing VIBATIV in the U.S., which would adversely affect our business and financial condition and the price of our securities could fall. In the event we were to market, sell and distribute any additional products, we would face similar challenges and risks, which could adversely affect our business and financial condition and the price of our securities could fall.

Any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates may face, would harm our business and the price of our securities could fall.

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs. The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- failure of our partners to advance our product candidates through clinical development;

- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

Our ongoing drug discovery and development efforts might not generate additional successful product candidates or approvable drugs.

Our compounds in clinical trials and our future leads for potential drug compounds are subject to the risks and failures inherent in the development of pharmaceutical products. These risks include, but are not limited to, the inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates.

Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies.

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later non-clinical or clinical studies. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, varying levels of adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Clinical and non-clinical studies of product candidates often reveal that it is not possible or practical to continue development efforts for these product candidates. In addition, the design of a clinical trial can determine whether its results will support regulatory approval and flaws in the design of a clinical trial may not become apparent until the clinical trial is well underway. If our ongoing clinical studies for our current product candidates, such as the Phase 3 development program for revefenacin for the treatment of COPD and the earlier stage clinical studies for our gastrointestinal (GI)-targeted JAK inhibitor program or our NEP inhibitor program, are substantially delayed or fail to meet their designated end points we may not receive regulatory approval of any of these product candidates. In addition, our product candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

If our product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

The FDA must approve any new medicine before it can be marketed and sold in the U.S. We will not obtain this approval for a product candidate unless and until the FDA approves a new drug application ("NDA"). We, or our collaborative partners, must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. FDA or foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. The processes by which regulatory approvals are obtained from the FDA and foreign regulatory authorities to market and sell a new product are complex, require a number of years, depend upon the type, complexity and novelty of the product candidate and involve the expenditure of substantial resources for research, development and testing. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance may lead to increased uncertainty regarding the approvability of new drugs. In addition, over the past decade, the FDA has implemented additional standards for approval of new drugs, including recommended advisory committee meetings for new molecular entities, and formal risk evaluation and mitigation requirements at the FDA's discretion. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed or impose significant restrictions or limitations on use of such product.

In addition, in order to market our medicines in foreign jurisdictions, we, or our collaborative partners, must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

We rely on a single manufacturer for the Active Pharmaceutical Ingredient ("API") for telavancin and a separate, single manufacturer for VIBATIV drug product supply. Our business will be harmed if either of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.

We have a single source of supply of API for telavancin and another, separate single source of supply of VIBATIV drug product. If, for any reason, either single-source third-party manufacturer of telavancin API or of VIBATIV drug product is unable or unwilling to perform, or if the performance of either does not meet regulatory requirements, including maintaining current Good Manufacturing Practice ("cGMP") compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API or drug product in a timely manner. We expect it would take approximately 24 months for an alternative manufacturer to be qualified by us and begin producing drug product for us and we currently have sufficient quantities of VIBATIV drug product on hand to meet our anticipated needs only through approximately December 2016. Currently we anticipate receipt of additional manufactured drug product supply during the third quarter of 2016 and plan to manufacture additional drug product. Given the time required to locate and qualify another acceptable drug product manufacturer, any supply delay, suspension or cessation in the manufacture and release of VIBATIV drug product by Hospira (whether or not resulting from the inability to release lots already manufactured or the inability to manufacture additional lots, or otherwise) would adversely affect the commercialization of VIBATIV and our obligations to our partners, and the price of our securities could fall. Similarly, any inability to acquire sufficient quantities of API in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV and our ability to satisfy our obligations to our partners and the price of our securities could fall.

Our previous VIBATIV commercialization partner (at the time with Innoviva) failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization for well over a year. We currently have an agreement with Hospira to supply VIBATIV drug product, which was entered into May 2012. In June 2013, the FDA approved Hospira as a VIBATIV drug product manufacturer. Pfizer acquired Hospira in 2015 and we cannot predict whether the acquisition will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product. We are currently in discussions with Hospira to extend the term of our agreement, which expires at the end of 2017. If we are unable to extend our supply relationship with Hospira, we would need to arrange for the advance manufacture and purchase of drug product in order to manage the transition to a new supplier and such advance manufacturing and purchasing entails significant uncertainties, including the risk of purchasing excess or insufficient quantities relative to our future needs and the possible expiration of excess inventories. Any difficulties in continuing or transitioning our single source suppliers would adversely affect the commercialization of VIBATIV and our ability to satisfy our obligations to our partners and the price of our securities could fall.

We rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.

We have limited in-house production capabilities for preclinical and clinical study purposes, and depend primarily on a number of third-party API and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into acceptable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay preclinical and clinical studies and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;
- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA with respect to VIBATIV and failure to comply with these regulations and requirements may subject us to penalties that may adversely affect our financial condition or our ability to commercialize VIBATIV.

With VIBATIV approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing. Prescription drug advertising and promotion are closely scrutinized by FDA, including substantiation of promotional claims, disclosure of risks and safety information, and the use themes and imagery in advertising and promotional materials. As with all companies selling and marketing products regulated by the FDA in the U.S., we are prohibited from promoting any uses of VIBATIV that are outside the scope of use that has been expressly approved by FDA as safe and effective on the VIBATIV label.

Furthermore, the U.S. labeling for VIBATIV contains a boxed warning. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings and FDA regulations prohibit the use of reminder advertising for VIBATIV. In addition, the VIBATIV labeling for hospital-acquired and ventilator associated bacterial pneumonia ("HABP/VABP") in the U.S. and the European Union specifies that VIBATIV should be reserved for use when alternative treatments are not suitable. These restrictions add complexity to the marketing of VIBATIV.

The FDA has also required that we evaluate the safety of VIBATIV use during pregnancy by developing and maintaining a prospective, observational pregnancy exposure registry study conducted in the United States. This postmarketing study remains ongoing and will continue through the end of 2019. In addition, the FDA has required that we comply with a risk evaluation and mitigation strategy ("REMS") to inform healthcare providers and patients of key risks via a communication plan. Healthcare providers periodically receive letters reminding them of the major potential risks associated with VIBATIV and patients receive a medication guide with each course of antibiotic use. The healthcare provider letter is also available on the product website. The REMS stipulates that we make assessments of the efficacy of these educational efforts and provide reports to FDA at specified intervals.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at a contract manufacturer's facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") and other regulatory bodies with respect to VIBATIV, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business.

Regulatory approval for our product candidates, if any, may include similar or other limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies.

Any failure to maintain regulatory approval will limit our ability to commercialize VIBATIV or our product candidates and if we fail to comply with FDA regulations and requirements regarding VIBATIV or any of our product candidates, the FDA could potentially take a number of enforcement actions against us, including the issuance of untitled letters, warning letters, preventing the introduction or delivery of VIBATIV into interstate commerce in the United States, misbranding charges, product seizures, injunctions, and civil monetary penalties, which would materially and adversely affect our business and financial condition and may cause the price of our securities to fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the U.S. and throughout the world also apply to the commercialization of any partnered products by our collaboration partners, and such regulatory actions and oversight may limit our collaboration partners' ability to commercialize such products, which could materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

We may face competition from companies seeking to market generic versions of VIBATIV.

For a discussion of the risk of generic competition to VIBATIV, please see the following risk factor below "*If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market*."

If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, we may not be able to develop or commercialize our partnered product candidates as planned.

We have an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5 HT4 program, covering the European Union, Russia, China, Mexico and certain other countries. In October 2012, we (at the time with Innoviva) also entered into a research collaboration and license agreement with Merck & Co., Inc. ("Merck") to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease, which Merck terminated in September 2013. We also have commercialization agreements with various partners for the commercialization of VIBATIV outside of the United States, including Canada, Middle East, North Africa, Israel, Russia, China and India. In August 2016, we and Clinigen reached a mutual decision that Clinigen will return commercial rights to market and distribute VIBATIV in the European Union to Theravance Biopharma. The Alfa Wassermann and Clinigen agreements were assigned to us in the Spin-Off. The Alfa Wassermann agreement provides research and development funding for the program under license. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA revefenacin (TD-4208). Under the terms of the agreement, we and Mylan will co-develop nebulized revefenacin for COPD and other respiratory diseases. In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (collectively with Millennium, "Takeda"), in order to establish a collaboration for the development and commercialization of TD-8954, a selective 5-HT4 receptor agonist. Under the terms of the Agreement, Takeda will be responsible for worldwide development and commercialization of TD-8954. The closing of the transactions contemplated by the Agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). In connection with these agreements, these parties have certain rights regarding the use of its patents and technology with respect to the compounds in our development programs, including development and marketing rights.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they or we may terminate our partnership with them as Astellas did in January 2012 with its VIBATIV agreement, as Merck did in September 2013 with the cardiovascular disease collaboration and as we and Clinigen did in August 2016 with the commercialization agreement for VIBATIV in the European Union and certain other European countries. In either event, we may be unable to assume the development and commercialization responsibilities covered by the agreements or enter into alternative arrangements with a third-party to develop and commercialize such product candidates. If a partner elected to promote alternative products and product candidates such as its own products and product candidates in preference to those licensed from us, does not devote an adequate amount of time and resources to our product candidates or is otherwise unsuccessful in its efforts with respect to our products or product candidates, the development and commercialization of product candidates covered by the agreements could be delayed or terminated, and future payments to us could be delayed, reduced or eliminated and our business and financial condition could be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of our partners. If a partner terminates or breaches its agreements with us, otherwise fails to complete its obligations in a timely manner or alleges that we have breached our contractual obligations under these agreements, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. Furthermore, termination of an agreement by a partner could have an adverse effect on the price of our ordinary shares or other securities even if not material to our business.

Because GSK is a strategic partner of Innoviva, a strategic partner of TRC and a significant shareholder of us, it may take actions that in certain cases are materially harmful to our business and to our other shareholders.

Based on our review of publicly available filings, as of June 30, 2016, GSK beneficially owned approximately 20.2% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the strategic alliance agreement and under the collaboration agreement assigned to TRC (the "GSK-Innoviva Agreements") that may cause GSK's interests to differ from the interests of us and our other shareholders. In particular, if the Closed Triple or a MABA/ICS in either the U.S. or the European Union is approved, GSK's diligent efforts obligations under the GSK-Innoviva Agreements with regard to commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK-Innoviva Agreements. Following such regulatory approval, GSK's commercialization efforts will be guided by a portfolio approach across products in which we have an indirect interest through TRC and products in which we have no interest. Accordingly, GSK's commercialization efforts may have the effect of reducing the value of our interest in TRC. Furthermore, GSK has a substantial respiratory product portfolio in addition to the products covered by the GSK-Innoviva Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with Innoviva and TRC. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK-Innoviva Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK-Innoviva Agreements, GSK

may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations and the price at which GSK might seek to acquire us may not reflect our true value. Although the actions GSK may take to acquire us are limited under our governance agreement with GSK (the "Governance Agreement"), this agreement will expire on December 31, 2017. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK-Innoviva Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. In addition, GSK could also seek to challenge our or Innoviva's post-Spin-Off operations as violating or allowing it to terminate the GSK-Innoviva Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Innoviva and us entered into in connection with the Spin-Off, or otherwise violating its legal rights. While we believe our operations fully comply with the GSK-Innoviva Agreements, the master agreement and applicable law, there can be no assurance that we or Innoviva will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any other action or inaction by either GSK or Innoviva that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between those parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for Innoviva's partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK-Innoviva Agreements or the relationship/partnership between Innoviva and GSK could result in significant reduction in the market price of our securities and other material harm to our business.

Agreements entered into with or for the benefit of GSK in connection with the Spin-Off may significantly restrict our business and affairs.

On March 3, 2014, in connection with the Spin-Off, we, Innoviva and GSK entered into a number of agreements that may significantly restrict our business and affairs. In particular, we, Innoviva and GSK entered into a three-way master agreement (the "Master Agreement") that, among other things, requires GSK's consent to make any changes to (A) the Separation and Distribution Agreement and ancillary agreements that would, individually or in the aggregate, reasonably be expected to adversely affect GSK in any material respect or (B) the TRC Limited Liability Company Agreement, which consent is not to be unreasonably withheld, conditioned or delayed, provided that GSK may withhold, condition or delay such consent in its sole discretion with respect to certain sections of the TRC Limited Liability Company Agreement and any changes to the governance structure of TRC, the confidentiality restrictions, the consent rights, and the transfer restrictions in the TRC Limited Liability Company Agreement. We and GSK also entered into (i) the Governance Agreement that, among other things, provides share purchase rights to GSK and exempts GSK from triggering our Rights Agreement until December 31, 2017, (ii) a registration rights agreement that gives GSK certain registration rights with respect to our ordinary shares held by GSK and (iii) an extension agreement that extends to us certain restrictive covenants similar to those applicable to Innoviva under the GSK-Innoviva Agreements. There can be no assurance that these restrictions will not materially harm our business, particularly given that GSK's interests may not be aligned with the interests of our business or our other shareholders.

We depend on third parties in the conduct of our clinical studies for our product candidates.

We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of our non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices ("GCPs") and other regulations as required by the FDA and foreign regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

The FDA, and equivalent authorities in other countries, enforces GCPs and other regulations through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs (or other equivalent regulations outside the United States), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or equivalent authorities in other countries, or we, the FDA, or equivalent authorities in other countries may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and the price of our securities could fall.

We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing, receiving approval for or commercializing products before or more successfully than we do.

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery, development and commercialization of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety using our proprietary insight in chemistry, biology and multivalency, where applicable. We expect that any medicines that we commercialize with or without our collaborative partners will compete with existing or future market-leading medicines.

Many of our current and potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development, and, more recently, commercialization, to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- develop and effectively implement commercialization strategies, with or without collaborative partners; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

Pharmaceutical companies, including companies with which we collaborate, may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA or equivalent regulatory approval outside the United States or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. VIBATIV must demonstrate these advantages in certain circumstances, as it competes with vancomycin and linezolid, relatively inexpensive generic drugs that are manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. In addition, sales of a generic version of daptomycin could begin in 2016. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

Certain of our directors and officers may have actual or potential conflicts of interest because of their equity ownership in Innoviva, which actual or potential conflicts may harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.

Certain of our directors and executive officers hold shares of Innoviva's common stock or rights to acquire such shares, and these holdings may be significant for some of these individuals compared to their total assets. This ownership of Innoviva common stock by our officers and most of our directors may create, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Innoviva and for us. For example, potential or actual conflicts could arise relating to: our relationship with Innoviva, including Innoviva's and our respective rights and obligations under agreements entered into in connection with the Spin-Off; Innoviva's management of TRC, particularly given that we and Innoviva have different economic interests in TRC; and corporate opportunities that may be available to both companies in the future. Although we and Innoviva have implemented policies and procedures to identify and properly address such potential and actual conflicts of interest, there can be no assurance that, when such conflicts are resolved in accordance with applicable laws, such conflicts of interest will not harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Innoviva.

If we lose key management or scientific personnel, or if we fail to attract and retain key employees, our ability to discover and develop our product candidates and commercialize VIBATIV and any other products that may be approved in the future will be impaired.

We are highly dependent on principal members of our management team and scientific staff, and in particular, our Chief Executive Officer, Rick E Winningham, to operate our business. Mr. Winningham has significant pharmaceutical industry experience. The loss of Mr. Winningham's services could impair our ability to discover, develop and commercialize new medicines.

If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our discovery, development and commercialization activities, which may cause the price of our securities to fall.

In addition, our U.S. operating subsidiary's facility and most of its employees are located in northern California, headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market is intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities and the price of our securities could fall.

Our business and operations would suffer in the event of significant disruptions of information technology systems or security breaches.

We rely extensively on computer systems to maintain information and manage our finances and business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information and personal information) and it is critical that we maintain the confidentiality and integrity of such confidential information. Although we have security measures in place, our internal information technology systems and those of our CROs and other service providers are vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, service providers and/or business partners, from cyber-attacks by malicious third parties, and/or from, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Significant disruptions of information technology systems or security breaches could adversely affect our business operations and result in financial, legal, business and reputational harm to us, including significant liability and/or significant disruption to our business. If a disruption of information technology systems or security breach results in a loss of or damage to our data or regulatory applications, unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, or other harm to our business, we could incur liability and reputational harm, we could be required to comply with federal and/or state breach notification laws and foreign law equivalents, the further development of our product candidates could be delayed and the price of our securities could fall. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Although we have security and fraud prevention measures in place, we have been subject to immaterial payment fraud activity. Moreover, there can be no assurance that such security measures will prevent service interruptions or security breaches that could adversely affect our business.

Our U.S. operating subsidiary's facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our U.S. operating subsidiary's facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore will be vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where appropriate, we plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory shareholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). Therefore, the information that we intend to provide shareholders for as long as we continue to be an emerging growth company will be different than what is available with respect to some other public companies. We cannot predict if investors will find our ordinary shares less attractive because we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We were an emerging growth company for all of 2015 and will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (ii) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (iv) December 31, 2019, the end of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement filed under the Securities Act.

Our historical financial information prior to the Spin-Off may not reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows.

Our historical financial information prior to the Spin-Off does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows. This is primarily a result of the following factors:

- prior to the Spin-Off, our business was operated by Innoviva as part of its broader corporate organization rather than as a stand-alone company, and our business was able to leverage Innoviva's financial resources and creditworthiness;
- prior to the Spin-Off, certain general administrative functions were performed by Innoviva for the combined entity. Our historical consolidated financial statements reflect allocations of costs for services shared with Innoviva. These allocations may differ from the costs we will incur for these services as an independent company;
- holding other factors constant, our cost of capital as a stand-alone company is likely higher on average than Innoviva's cost of capital was as a combined business prior to the Spin-Off;
- following the Spin-Off, we are responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and listed and registered securities; and
- having separated from Innoviva, there is a risk that we may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Innoviva.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we became subject following the Spin-Off. If we are unable to achieve and maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

We are subject to the reporting and other obligations under the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which will require annual management assessments of the effectiveness of our internal control over financial reporting. When and if we become a "large accelerated filer" and are no longer an "emerging growth company," each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources.

In addition, during the second quarter of 2016, we implemented a new enterprise resource planning ("ERP") system and continue to make modifications and enhancements to the ERP system. Our ERP system is critical to our ability to accurately maintain books and records, record transactions, provide important information to our management and prepare our financial statements. Such an implementation is complex and difficult and requires us to address a number of challenges including data conversion, system cutover and user training. As a result, it represents a major undertaking financially and from a management and personnel perspective. Our business and results of operations may be adversely affected if we experience operating problems and/or cost overruns relating to the ERP implementation (including subsequent modifications and enhancements), or if the ERP system and the associated process changes do not give rise to the benefits that we expect. Additionally, if we encounter problems with the ERP system (including all modifications and enhancements) as implemented or if the system does not operate as intended, it could be disruptive and adversely affect our operations and results of operations, including our ability to report accurate and timely financial results and the effectiveness of our internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited history operating as an independent company upon which you can evaluate us.

We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited operating history as an independent company upon which you can evaluate us. While our biopharmaceutical business has constituted a substantial part of the historic operations of Innoviva, we did not operate as a stand-alone company without the right to receive potential royalty revenue derived from Innoviva's GSK-Partnered Respiratory Program (the "Royalty Business") until the Spin-Off. As a new independent company, our ability to satisfy our obligations and achieve profitability will be primarily dependent upon the future performance of our biopharmaceutical business, and we do not rely upon the revenues, capital resources and cash flows of the Royalty Business remaining with Innoviva.

We may be treated as a U.S. corporation for U.S. federal income tax purposes.

For U.S. federal income tax purposes, a corporation generally is considered tax resident in the place of its incorporation. Theravance Biopharma is incorporated under Cayman Islands law and established tax residency in Ireland effective July 1, 2015. Therefore, it should be a non-U.S. corporation under this general rule. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code"), contains rules that may result in a foreign corporation being treated as a U.S. corporation for U.S. federal income tax purposes. The application of these rules is complex and there is little guidance regarding certain aspects of their application.

Under Section 7874 of the Code, a corporation created or organized outside the U.S. will be treated as a U.S. corporation for U.S. federal tax purposes if (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a U.S. corporation, (ii) the former shareholders of the acquired U.S. corporation hold at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the U.S. acquired corporation, and (iii) the foreign corporation's "expanded affiliated group" does not have "substantial business activities" in the foreign corporation's country of incorporation relative to its expanded affiliated group's worldwide activities. For this purpose, "expanded affiliated group" generally means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the stock by vote and value, and "substantial business activities" generally means at least 25% of employees (by number and compensation), assets and gross income of our expanded affiliated group are based, located and derived, respectively, in the country of incorporation.

We do not expect to be treated as a U.S. corporation under Section 7874 of the Code, because we do not believe that the assets contributed to us by Innoviva constituted "substantially all" of the properties of Innoviva (as determined on both a gross and net fair market value basis). However, the Internal Revenue Service ("IRS") may disagree with our conclusion on this point and assert that, in its view, the assets contributed to us by Innoviva did constitute "substantially all" of the properties of Innoviva. In addition, there could be legislative proposals to expand the scope of U.S. corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could apply retroactively and could result in Theravance Biopharma being treated as a U.S. corporation.

If it were determined that we should be treated as a U.S. corporation for U.S. federal income tax purposes, we could be liable for substantial additional U.S. federal income tax on our post-Spin-Off taxable income. In addition, payments of dividends to non-U.S. holders may be subject to U.S. withholding tax.

Taxing authorities may challenge our structure and transfer pricing arrangements.

We are incorporated in the Cayman Islands, maintain subsidiaries in the Cayman Islands, United States, the United Kingdom and Ireland, and effective July 1, 2015, we migrated our tax residency from the Cayman Islands to Ireland. Due to economic and political conditions various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions such as the Cayman Islands and Ireland, together with intra-group transfer pricing agreements. Taxing authorities may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. We may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future which could result in reduced cash flows and have a material adverse effect on our business, financial condition and growth prospects.

If we are required to indemnify Innoviva, or if we are not able to collect on indemnification rights from Innoviva, our business prospects and financial condition may be harmed.

We agreed to indemnify Innoviva from and after the Spin-Off with respect to (i) all debts, liabilities and obligations transferred to us in connection with the Spin-Off (including our failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off), (ii) any misstatement or omission of a material fact resulting in a misleading statement in our Information Statement distributed to Innoviva stockholders in connection with the Spin-Off and (iii) any breach by us of certain agreements entered into with Innoviva in connection with the Spin-Off (namely, the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement). We are not aware of any existing indemnification obligations at this time, but any such indemnification obligations that may arise could be significant. Under the terms of the Separation and Distribution Agreement, Innoviva agreed to indemnify us from and after the Spin-Off with respect to (i) all debts, liabilities and obligations retained by Innoviva after the Spin-Off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off) and (ii) any breach by Innoviva of the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement. Our and Innoviva's ability to satisfy these indemnities, if called upon to do so, will depend upon our and Innoviva's future financial strength. If we are required to indemnify Innoviva, or if we are not able to collect on indemnification rights from Innoviva, our business prospects and financial condition may be harmed.

RISKS RELATED TO LEGAL AND REGULATORY UNCERTAINTY

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 30, 2016, we or one of our wholly-owned subsidiaries owned 423 issued United States patents and 1,571 granted foreign patents, as well as additional pending United

States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize products. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a company may submit an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act to market a generic version of an approved drug. Because a generic applicant does not conduct its own clinical studies, but instead relies on the FDA's finding of safety and effectiveness for the approved drug, it is able to introduce a competing product into the market at a cost significantly below that of the original drug. Although we have multiple patents protecting VIBATIV until at least 2021 the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, generic applicants could potentially submit "paragraph IV certifications" to FDA stating that such patents are invalid or will not be infringed by the applicant's product. We have not received any such paragraph IV notifications but if any competitors successfully challenge our patents, we would face substantial competition. If we are not able to compete effectively against such future competition, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights without authorization. There are third-party patents that may cover materials or methods for treatment related to our product candidates. At present, we are not aware of any patent infringement claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third-party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us or our partners may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense against these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed and the price of our securities could fall.

If the efforts of our partners or future partners to protect the proprietary nature of the intellectual property related to collaboration assets are not adequate, the future commercialization of any medicines resulting from collaborations could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.

The risks identified in the two preceding risk factors may also apply to the intellectual property protection efforts of our partners or future partners and to GSK with respect to the GSK-Partnered Respiratory Programs in which we hold an economic interest. To the extent the intellectual property protection of any partnered assets are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset, particularly those of the GSK-Partnered Respiratory Programs in which we hold an economic interest, could harm our business and cause the price of our securities to fall.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our medicines.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products and have likely increased with the commercial reintroduction of VIBATIV. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. The VIBATIV prescribing information describes several potential adverse effects observed during clinical trials, including increased mortality versus vancomycin in patients with HABP/VABP who had pre-existing moderate to severe renal impairment, decreased clinical response in patients with cSSSI who had pre-existing moderate/severe renal impairment, and other renal adverse events. The prescribing information includes a black box warning regarding increased mortality in patients with pre-existing moderate/severe renal impairment who were treated with VIBATIV for HABP/VABP, new onset or worsening renal impairment, use in women of childbearing potential or during pregnancy and adverse developmental outcomes observed in 3 animal species. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class, asserting injuries based both on potential adverse effects described in the label as well as adverse events not yet observed. Also, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully and the price of our securities could fall.

Changes in healthcare law and implementing regulations, including government restrictions on pricing and reimbursement, as well as healthcare policy and other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our or our collaborators' ability to set and collect a price we believe is reasonable for our product;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The pricing and reimbursement environment for VIBATIV and any future products may change in the future and become more challenging due to, among other reasons, policies advanced by the current or any new presidential administration, federal agencies, new healthcare legislation passed by Congress or fiscal challenges faced by all levels of government health administration authorities. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of VIBATIV and other products we may bring to market, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together the "Healthcare Reform Act"), is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Healthcare Reform Act contains a number of provisions that impact our business and operations. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicare Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Details of the changes to the Medicaid Drug Rebate program and the 340B program are discussed below under the risk factor "— *If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.*" In particular, on February 1, 2016, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicare and Medicaid programs, issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. Congress could enact additional legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate program. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Some states have elected not to expand their Medicaid programs by raising the income limit to 133% of the federal poverty level, as is permitted under the Healthcare Reform Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales, business and financial condition. Where Medicaid patients receive insurance coverage under any of the new options made available through the Healthcare Reform Act, manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, which could impact manufacturer revenues. In addition, the federal government has also announced delays in the implementation of key provisions of the Healthcare Reform Act. The implications of these delays for our sales, business and financial condition, if any, are not yet clear.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved.

Beginning on April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, were reduced by 2% under the sequestration (i.e., automatic spending reductions) as required by federal law, which requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The law caps the cuts to Medicare payments for items and services at 2% and this will continue to 2025. As long as these cuts remain in effect, they could adversely impact payment for VIBATIV and our product candidates. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we have obligations to report average sales price under the Medicare program.

Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions.

The Healthcare Reform Act made significant changes to the Medicaid Drug Rebate program, such as expanding rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well and changing the definition of average manufacturer price. The Healthcare Reform Act also increased the minimum Medicaid rebate; changed the calculation of the rebate for certain innovator products that qualify as line extensions of existing drugs; and capped the total rebate amount for innovator drugs at 100% of the average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government.

On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. These regulations became effective on April 1, 2016. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The Healthcare Reform Act expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Changes to the definition of average manufacturer price and the Medicaid rebate amount under the Healthcare Reform Act and CMS's final regulations implementing those changes also could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. The Health Resources and Services Administration ("HRSA") has issued a proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B program. HRSA is expected to issue additional proposed regulations in 2016. Any final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report average sales price information each quarter to CMS for certain categories of drugs that are paid under the Medicare Part B program. Manufacturers calculate the average sales price based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Statutory or regulatory changes or CMS binding guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations. Also, the Medicare Part B drug payment methodology is subject to change based on potential demonstration projects undertaken by CMS or potential legislation enacted by Congress. For example, in March 2016, CMS proposed to conduct a demonstration project that would reduce the Medicare payment rates for most Part B drugs from average sales price plus 6% to average sales price plus 2.5% plus $16.80 per drug per day for approximately half of the country. CMS indicated that it intends to implement this project in 2016, followed by a second phase of the demonstration in 2017 that would apply "value-based purchasing" tools to make further adjustments to payment rates. A final decision on this proposal is expected later this year.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B drug discount program.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted any false price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS and the OIG have pursued manufacturers that were alleged to have failed to report these data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by the VA, Department of Defense, Public Health Service, and Coast Guard and certain federal grantees, we are required to participate in the Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program, established under Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make VIBATIV available for procurement on an FSS contract and charge a price that is no higher than the Federal Ceiling Price ("FCP"), which is a price calculated pursuant to a statutory formula. The FCP keys off of a calculated price point called the "non-federal average manufacturer price" ("Non-FAMP"), which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information. The FSS contract also contains extensive disclosure and certification requirements.

Under Section 703 of the National Defense Authorization Act for FY 2008, we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. If we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and any response to government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions (which could include civil and/or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as

amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater privacy protections.

EU member states and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EU Data Protection Directive imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted similar restrictions. Data protection authorities from the different EU member states may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the EU. Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the U.S., a decision of the European Court of Justice in the *Schrems* case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce (DOC) to replace the invalidated Safe Harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies will be able to certify to the U.S. Department of Commerce their compliance with the privacy principles of the Privacy Shield starting on August 1, 2016. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation entered into force on May 24, 2016 and will apply from May 25, 2018. The Regulation will introduce new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules. The EU General Data Protection Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

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

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

- The federal healthcare Anti-Kickback Statute prohibits any person from, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchasing, leasing, ordering or arranging for or recommending of any good or service for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute is subject to evolving interpretation and has been applied by government enforcement officials to a number of common business arrangements in the pharmaceutical industry. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the statute or specific intent to violate it. There are a number of statutory exemptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. We seek to comply with the available statutory exemptions and safe harbors whenever possible, but our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants or patient assistance programs.

- The federal civil False Claims Act imposes civil penalties, and provides for whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government. In recent years, several pharmaceutical and other healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly submitting false or misleading pricing information to government health care programs and providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal enforcement agencies also have showed increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. Other companies have faced enforcement actions for causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $5,500 to $11,000 per false claim or statement. As a result of a recent interim final rule issued by the Department of Justice (DOJ), the penalties assessed after August 1, 2016 for violations occurring after November 2, 2015 will increase to per claim or statement penalties of $10,781 to $21,563. Because of the potential for large monetary exposure, healthcare and pharmaceutical companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Companies may be required, however, to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Criminal prosecution is also possible for making or presenting a false or fictitious or fraudulent claim to the federal government.

- HIPAA, among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, imposes annual reporting requirements on certain manufacturers of drugs, devices, or biologics for payments and other transfers of value by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1 million per year for "knowing failures." Manufacturers must submit reports by the 90th day of each calendar year.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Several states also require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing-related activities, including the provision of gifts, meals, or other items to certain health care providers. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.

- Similar restrictions imposed on the promotion and marketing of medicinal products in the EU and other countries, including restrictions prohibiting the promotion of a compound prior to its approval. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we may decide not to directly promote or market our products, inappropriate activity by our any international distribution partners could have implications for us.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that we or our partners may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we do or expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Our business and operations, including the use of hazardous and biological materials may result in liabilities with respect to environmental, health and safety matters.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products, including hazardous waste. Federal, state and local laws and regulations govern the use, manufacture, management, storage, handling and disposal of hazardous materials and wastes. We may incur significant additional costs or liabilities to comply with, or for violations of, these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. Further, in the event of a release of or exposure to hazardous materials, including at the sites we currently or formerly operate or at sites such as landfills where we send wastes for disposal, we could be held liable for cleanup costs or damages or subject to other costs or penalties and such liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials or under environmental laws. Compliance with or liability under applicable environmental laws and regulations or with respect to hazardous materials may be expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

RISKS RELATING TO OUR ORDINARY SHARES

The market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares.

Our ordinary shares began trading on June 3, 2014, and the market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares. To date, there is limited securities analyst coverage of our company. Limited securities analyst coverage of our company and shares is likely to reduce demand for our shares from potential investors, which likely will reduce the market price for our shares. To the extent that historically low trading volumes for our ordinary shares continues, our stock price may fluctuate significantly more than the stock market as a whole or the stock prices of similar companies. Without a larger public float of actively traded shares, our ordinary shares are likely to be more sensitive to changes in sales volumes, market fluctuations and events or perceived events with respect to our business, than the shares of common stock of companies with broader public ownership, and as a result, the trading prices for our ordinary shares may be more volatile. Among other things, trading of a relatively small volume of ordinary shares may have a greater effect on the trading price than would be the case if our public float of actively traded shares were larger.

Market prices for securities of biotechnology and biopharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our ordinary shares involves substantial risk. By separating from Innoviva, there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Innoviva. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies.

The following are some of the factors that may have a significant effect on the market price of our ordinary shares:

- any adverse developments or results or perceived adverse developments or results with respect to the GSK-Partnered Respiratory Programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV;
- whether we achieve increased sales for VIBATIV;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development, are manufacturing or have commercialized;
- any adverse developments or agreements or perceived adverse developments or agreements with respect to the relationship of Innoviva or TRC, on the one hand, and GSK, on the other hand, including any such developments or agreements resulting from or relating to the Spin-Off;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners, including any such developments resulting from or relating to the Spin-Off;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- announcements with respect to governmental or private insurer reimbursement policies;
- announcements of equity or debt financings;
- economic and other external factors beyond our control;
- loss of key personnel;
- likelihood of our ordinary shares to be more sensitive to changes in sales volume, market fluctuations and events or perceived events with respect to our business due to our small public float;
- low public market trading volumes for our ordinary shares related in part to the concentration of ownership of our shares;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;

- delays in manufacturing adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the ordinary shares would likely drop significantly. A significant drop in the price of a company's securities often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

Concentration of ownership will limit your ability to influence corporate matters.

Based on our review of publicly available filings, as of June 30, 2016 GSK beneficially owned approximately 20.2% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 6.7% of our outstanding ordinary shares. Based on our review of publicly available filings, as of June 30, 2016 our three largest shareholders other than GSK collectively owned approximately 29.0% of our outstanding ordinary shares. GSK also has a right to maintain its percentage ownership in our company under the Governance Agreement, including by participating in offerings of our ordinary shares. These shareholders and GSK could control the outcome of actions taken by us that require shareholder approval, including a transaction in which shareholders might receive a premium over the prevailing market price for their shares.

Certain provisions in our constitutional documents may discourage our acquisition by a third-party, which could limit your opportunity to sell shares at a premium.

Our constitutional documents include provisions that could limit the ability of others to acquire control of us, modify our structure or cause us to engage in change-of-control transactions, including, among other things, provisions that:

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;
- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

These provisions could have the effect of depriving you of an opportunity to sell your ordinary shares at a premium over prevailing market prices by discouraging third parties from seeking to acquire control of us in a tender offer or similar transaction.

Our shareholders may face difficulties in protecting their interests because we are incorporated under Cayman Islands law.

Our corporate affairs are governed by our amended and restated memorandum and articles of association, by the Companies Law (2013 Revision) (as amended) of the Cayman Islands and by the common law of the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under the laws of the Cayman Islands are different from those under statutes or judicial precedent in existence in jurisdictions in the U.S. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the U.S., due to the different nature of Cayman Islands law in this area.

Shareholders of Cayman Islands exempted companies such as our company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Our Cayman Islands counsel, Maples and Calder, is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, the company will be the proper plaintiff in any claim based on a breach of duty owed to it, and a claim against (for example) the company's officers or directors usually may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a "fraud on the minority."

A shareholder may have a direct right of action against the company where the individual rights of that shareholder have been infringed or are about to be infringed.

There is uncertainty as to shareholders' ability to enforce certain foreign civil liabilities in the Cayman Islands.

We are incorporated as an exempted company limited by shares with limited liability under the laws of the Cayman Islands. A material portion of our assets are located outside of the United States. As a result, it may be difficult for our shareholders to enforce judgments against us or judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States or any state of the United States.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the United States predicated upon the civil liability provisions of the securities laws of the United States or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against Theravance Biopharma predicated upon the civil liability provisions of the securities laws of the United States or any State, on the grounds that such provisions are penal in nature. However, in the case of laws that are not penal in nature, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands' judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands' court, including the Grand Court of the Cayman Islands, may stay proceedings if concurrent proceedings are being brought elsewhere, which would delay proceedings and make it more difficult for our shareholders to bring action against us.

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

None.

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit	Filed Herewith	Incorporated by Reference	
			Form	Filing Date/Period End Date
3.1	Amended and Restated Memorandum and Articles of Association		10-12B	April 30, 2014
10.1*	License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Millennium Pharmaceuticals, Inc. dated June 8, 2016	X		
10.2	Amendment No. 1 to the License, Development, and Commercialization Agreement by and between Theravance Biopharma Ireland Limited and Clinigen Group PLC dated August 4, 2016	X		
31.1	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended	X		
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended	X		
32(1)	Certifications Pursuant to 18 U.S.C. Section 135	X		
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended June 30, 2016, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements	X		

* Confidential treatment has been requested for certain portions which are omitted in the copy of the exhibit electronically filed with the Securities and Exchange Commission. The omitted information has been filed separately with the Securities and Exchange Commission pursuant to Theravance Biopharma, Inc.'s application for confidential treatment.

(1) The certifications provided as Exhibit 32.1 are being furnished to accompany the Report pursuant to 18 U.S.C. § 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to 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.

Theravance Biopharma, Inc.

Date: August 8, 2016

/s/ Rick E Winningham

Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2016

/s/ Renee D. Gala

Renee D. Gala
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Listed and indexed below are all Exhibits filed as part of this report.

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Exhibit 10.1

EXECUTION VERSION

LICENSE AND COLLABORATION AGREEMENT

BY AND BETWEEN

THERAVANCE BIOPHARMA IRELAND LIMITED

AND

MILLENNIUM PHARMACEUTICALS, INC.

DATED JUNE 8, 2016

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (this "Agreement"), dated as of June 8, 2016 (the "Execution Date"), is by and between THERAVANCE BIOPHARMA IRELAND LIMITED, a corporation organized under the laws of the state of Ireland having a principal place of business at Fitzwilliam Hall, Fitzwilliam Place, Dublin 2 Ireland ("TBIL"), and MILLENNIUM PHARMACEUTICALS, INC., a Delaware corporation having a principal place of business at 40 Landsdowne Street, Cambridge, Massachusetts, United States 02139 ("Takeda") (each, a "Party" and collectively, the "Parties").

WHEREAS, TBIL has discovered and is developing its proprietary compound referred to by TBIL as TD-8954;

WHEREAS, Takeda possesses knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products for use in the Field in the Territory (each as defined below); and

WHEREAS, TBIL and Takeda desire to establish a collaboration for the research, development and commercialization of products containing the Compound (as defined below), subject to and in accordance with the terms hereof.

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

ARTICLE I
DEFINITIONS

1.1 Definitions. Capitalized terms used in this Agreement shall have the meanings ascribed to such terms in this Agreement, including as set forth in this Section 1.1:

"Abandonment Notice" has the meaning set forth in Section 12.3(d).

"Affiliate" means, with respect to any Person, another Person which controls, is controlled by, or is under common control with such Person for so long as such control exists. For purposes of this definition, "control" (including, with correlative meanings, "controlled by," "controlling" and "under common control with") means (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly of more than fifty percent (50%) of the voting securities or other comparable equity interests (or such lesser percentage which is the maximum allowed to be owned by a foreign investor in a particular jurisdiction; provided that such foreign investor has the power to direct the management and policies of such entity).

"Alliance Manager" means, for each Party, an employee a Party or any of its Affiliates selected to serve as the primary point of contact for the Parties to exchange

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information, facilitate communication, coordinate the Parties' activities under this Agreement and provide day-to-day support to the Committees, as set forth herein.

"Applicable Laws" means all applicable laws, statutes, rules, regulations, orders, directives, decisions, judgments, injunctions, guidelines, ordinances or other pronouncements of any Governmental Authority.

"Aggregate Sales Milestone Event" has the meaning set forth in Section 8.2(c).

"Aggregate Sales Milestone Payment" has the meaning set forth in Section 8.2(c).

"Audited Party" has the meaning set forth in Section 8.14(a).

"Auditing Party" has the meaning set forth in Section 8.14(a).

"AW Development and Collaboration Agreement" means the [***] Agreement between Theravance Biopharma R&D, Inc. and Alfa Wassermann S.p.A., dated October 1, 2012, as amended or as may be amended from time to time.

"Business Day" means any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, U.S., Dublin, Ireland or Tokyo, Japan are authorized or required by Applicable Law to remain closed.

"Calendar Quarter" means for each Calendar Year, each of the three (3)-month periods ending March 31, June 30, September 30 and December 31; provided that the first Calendar Quarter under this Agreement shall extend from the Effective Date to the end of the first calendar quarter during which the Effective Date occurs, and the last Calendar Quarter under this Agreement shall end upon the effective date of the termination and/or expiration of this Agreement.

"Calendar Year" means each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31; provided that the first Calendar Year under this Agreement shall extend from the Effective Date to December 31 of the calendar year during which the Effective Date occurs, and the last Calendar Year under this Agreement shall end upon the effective date of the termination and/or expiration of this Agreement.

"Clinical Trial" means a test or study in human subjects or patients that is required to obtain one (1) or more Regulatory Approvals. For clarity, "Clinical Trial" excludes any Post-Marketing Study.

"Closing" has the meaning set forth in Section 10.5(d)(iv).

"Collaboration" has the meaning set forth in Section 2.1.

"Combination Product" means any pharmaceutical product, including all forms, presentations, strengths, doses and formulations (including any method of delivery), containing the Compound in combination with at least one other therapeutically active ingredient, whether

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packaged together as separate doses or a fixed dose in the same therapeutic formulation but in any event sold as a single unit or a bundled product at a single price.

"Commercialize", "Commercializing" or "Commercialization" means all activities related to marketing, promotion, distribution, and sale, including detailing, advertising, sales force training, invoicing and booking sales, paying all governmental rebates which are due and owing, ordering, processing, invoicing, collection, distribution, receivables and returns, scientific and medical affairs, Post-Marketing Studies, post-approval supply chain security and brand protection, post-approval anti-counterfeiting enforcement actions (including Internet countermeasures, collaborating with law enforcement and seeking criminal restitution), Manufacturing for commercial sale and all post-Regulatory Approval activities for maintaining Regulatory Approvals. For clarity, "Commercialization" shall not include Development.

"Commercialization Plan" has the meaning set forth in Section 5.2.

"Commercially Reasonable Efforts" means, with respect to an objective or obligation of a Party under this Agreement, those good faith, diligent efforts and resources (including financial resources) to achieve such objective or satisfy such obligation, that such Party would normally use to achieve a similar objective or satisfy a similar obligation under similar circumstances (it being understood and agreed that such efforts and resources shall be consistent with those efforts and resources commonly used by such Party under similar circumstances for similar compounds or products owned by it or to which it has similar rights, which compound or product, as applicable, is at a similar stage in its development or product life and is of similar market potential) taking into account: [***]. For clarity and notwithstanding anything to the contrary in this Agreement, "Commercially Reasonable Efforts" shall not take into account any [***]. Commercially Reasonable Efforts shall be determined on a [***], and it is anticipated that the [***] that constitute Commercially Reasonable Efforts with respect to a [***]. Notwithstanding anything to the contrary in this Agreement, neither Party shall be obligated to Develop, seek Regulatory Approval for, or Commercialize a Product in a manner that is inconsistent with Applicable Laws.

"Committee" means the JSC or any other working group established in accordance with Article II.

"Competing Product" means any [***].

"Competing Product Transaction" has the meaning set forth in Section 10.6(b).

"Competing Program" has the meaning set forth in Section 10.6(b).

"Competition Filings" has the meaning set forth in Section 10.5(d)(ii).

"Compound" means (a) the chemical compound coded by TBIL as TD-8954, the chemical structure of which is set forth in Exhibit 1.1(a) and (b) any salt form, hydrate, solvate, prodrug or ester form of the compound described in subsection (a).

"Confidential Information" has the meaning set forth in Section 9.1.

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"Confidentiality Agreement" means the Confidentiality Agreement (Mutual Disclosure) dated as of November 19, 2014 between Theravance Biopharma US, Inc. and Takeda Pharmaceuticals International, Inc.

"Contracting Party" has the meaning set forth in Section 3.4.

"Control" or "Controlled" means (a) with respect to any Intellectual Property, the legal authority or right (whether by ownership, license or otherwise, other than pursuant to a license or sublicense granted under this Agreement) of a Party or its Affiliates (as applicable) to grant a license or a sublicense in, to, or under such Intellectual Property to the other Party, and (b) with respect to any documents or materials, possession by and the ability of a Party or its Affiliates to provide the other Party with, or with access to, such documents and materials, each of the foregoing (a) and (b), as provided under this Agreement and without violating the terms of any agreement with a Third Party. For clarity, if a Party or its Affiliates can only grant a license or sublicense, or provide or provide access, of limited scope, for a specific purpose, or under certain conditions, "Control" or "Controlled" shall be construed to so limit such license, sublicense, or provision.

"Controlling Party" has the meaning set forth in Section 12.4(b).

"Co-Promote" has the meaning set forth in Section 5.6.

"Cover" means, with respect to a particular Patent, in the absence of a license, (a) with respect to any particular material, compound or product, the making, using, offering for sale, selling, importing or exporting of such material, compound or product; or (b) to the extent no material, compound or product is specified, the practicing of the applicable invention, discovery or process, in each case of (a) and (b) would infringe a Valid Claim of such Patent (or, in the case of a Patent that has not yet issued, would infringe such Valid Claim if such Patent were to issue).

"CMC Activities" means the activities conducted to generate the chemistry, manufacturing and controls section of an IND or application for Regulatory Approval.

"CVOT" means any cardiovascular outcomes trial in humans which is required by a Regulatory Authority to obtain or maintain Regulatory Approval in a jurisdiction, including such circumstances where such Regulatory Authority requires such trial be: (a) completed prior to submission of the application for Regulatory Approval; (b) conducted in connection with the granting of Regulatory Approval; or (c) conducted after the granting of Regulatory Approval in such jurisdiction.

"Designee" has the meaning set forth in Section 15.8(a)(xv).

"Develop," "Developing" or "Development" means all activities related to (a) research, non-clinical and pre-clinical studies, Clinical Trials, toxicology testing, statistical analysis or reporting, or preparing or submission of applications to support Clinical Trials or for Regulatory Approval, or (b) Manufacturing of compounds and products for such activities, including formulation, bulk production, fill/finish, manufacturing process development, or

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manufacturing or quality assurance technical support. For clarity, "Development" shall not include any Commercialization activities.

"Development Budget" has the meaning set forth in Section 4.2(c)(iii).

"Development Plan" has the meaning set forth in Section 4.2(a).

"Disclosing Party" has the meaning set forth in Section 9.1.

"Dispute" has the meaning set forth in Section 16.1.

"Effective Date" means the date on which HSR Act clearance has been obtained under Section 10.5(b).

"EMA" means the European Medicines Agency or any successor agency thereto.

"EU" means the member states of the European Union, as constituted from time to time.

"EU5" means France, Germany, Italy, Spain or the United Kingdom and including, in each case, the territories and possessions of each country.

"Exploit" and "Exploitation" means to make, have made, import, export, distribute, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, Manufacture, have Manufactured, register, enhance, improve or otherwise dispose of.

"FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

"FDA" means the U.S. Food and Drug Administration and any successor agency thereto.

"Field" means the treatment, prevention, palliation, or diagnosis of any disease or medical condition in humans.

"First Commercial Sale" means, on a country-by-country and Product-by-Product basis, the first sale of a Product under this Agreement by or on behalf of Takeda, its Affiliates or its Sublicensees to a Third Party for use, consumption or resale of the Product in a country in the Territory in the Field where Regulatory Approval of the Product has been obtained and where the sale results in a recordable Net Sale. Sale of a Product under this Agreement by Takeda to an Affiliate of Takeda or a Sublicensee of Takeda shall not constitute a First Commercial Sale unless such Affiliate or such Sublicensee is the end user of such Product or such sale otherwise results in a recordable Net Sale. Also, any transfer or disposition of a Product under this Agreement by or on behalf of Takeda, its Affiliates or its Sublicensees in a jurisdiction where Regulatory Approval for that Product has not yet been granted and is required for commercial sale shall not constitute a First Commercial Sale under this Agreement.

"First Submission" has the meaning set forth in Section 16.1(c)(ii).

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"Force Majeure" has the meaning set forth in Section 17.6.

"FTE" means the equivalent of a full-time employee's (i.e., one (1) fully-committed employee or multiple partially-committed employees aggregating to one full-time employee) work time actually spent on performance of the activities under this Agreement over a twelve (12)-month period (including normal vacations, sick days and holidays) (which shall be deemed to consist of 1900 hours per year). If any employee works partially on such activities under this Agreement and partially on other work in a given twelve (12)-month period, the full-time equivalent to be attributed to such employee's work hereunder shall be equal to the percentage of such employee's total work time in such period that such employee spent working on activities under this Agreement. In no event shall any one employee be counted as more than one (1) FTE. "FTE" excludes work time of general corporate or administrative personnel. For the avoidance of doubt, "FTE" only applies to employees of a Party, and does not apply to consultants or contract-employees of a Party.

"GAAP" means generally accepted accounting principles as applicable in the U.S., as consistently applied.

"Generic Product" means on a country-by-country and product-by-product basis (such product, the "Reference Product"), a pharmaceutical product (other than the Reference Product) that (a) is sold by any Third Party in such country (other than Takeda's licensees or sublicensees or any other Person in a chain of distribution originating from Takeda, its Affiliates or sublicensees), (b) contains the same active ingredients as the applicable Reference Product and if such Reference Product contains more than one active ingredient, the ratio of the dosage of each active ingredient in such pharmaceutical product as compared to the total dosage of all active ingredients in such pharmaceutical product is the same as such ratios for such Reference Product, and (c) is approved for marketing or sale in such country based on an NDA, an abbreviated new drug application submitted to the FDA pursuant to Section 505(j) of the FD&C Act or the foreign equivalent of any of the foregoing, in each case that relies on or references any finding of safety and/or effectiveness in the Regulatory Approval for such Reference Product, including pursuant to Section 505(b)(2) and/or 505(j) of the FD&C Act or any foreign equivalent thereof.

"Good Clinical Practices", GCP" or "cGCP" means the then-current good clinical practice standards throughout the Territory for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable, (a) the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the EU, (b) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (INDs), and (c) any similar Applicable Laws in any relevant country that provide for, among other things, assurances that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

"Good Laboratory Practices", "GLP" or "cGLP" means the then-current good laboratory practice standards throughout the Territory, including, as applicable, (a) the current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58 and (b) and similar Applicable Laws in any relevant country.

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"Good Manufacturing Practices", "GMP", or "cGMP" means the then-current good manufacturing practices throughout the Territory, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 210 and 211, (b) the Rules Governing Medicinal Products in the EU, Volume IV - Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, (c) the principles detailed in the ICH Q7 guidelines, and (d) any similar Applicable Laws in any relevant country.

"Government Proceeding" means any action, suit, claim, arbitration, mediation, proceeding, audit, hearing, inquiry, or investigation (in each case, whether civil, criminal, administrative or investigative) commenced or brought by any Governmental Authority.

"Governmental Authority" means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, local, county, city, municipal or other political subdivision of any such government or any supranational or multinational organization, in each case having jurisdiction over the applicable subject matter.

"Health Care Laws" means all Applicable Laws related to the business of the Parties such as: (i) the FD&C Act; (ii) Applicable Laws pertaining to privacy, data protection, data transfer and information security, and the regulations promulgated pursuant to such statutes; (iii) the Controlled Substances Act (21 U.S.C. § 801 et seq.); (iv) all applicable federal, state, local and all applicable foreign health care related fraud and abuse, false claims, and anti-kickback laws, including the U.S. Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the U.S. Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h) and similar gift and disclosure laws, the U.S. Civil False Claims Act (31 U.S.C. § 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including 18 U.S.C. §§ 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. § 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. § 17921 et seq.); (v) Medicare (Title XVIII of the Social Security Act); (vi) Medicaid (Title XIX of the Social Security Act); and (vii) all regulations promulgated under the laws described in the foregoing clauses (i)-(vi).

"Housemark" has the meaning set forth in Section 11.2(a).

"HSR Act" means, the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

"ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"IFRS" means International Financial Reporting Standards, as consistently applied.

"IND" means any Investigational New Drug application (including amendments and supplements thereto), as described in the FD&C Act, that is required to be filed with the

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FDA, and similar filings or submissions with Regulatory Authorities outside the U.S., each of which is necessary to commence or conduct clinical testing of pharmaceutical products in humans in the applicable country (including clinical trial applications and clinical trial exemptions).

"Indemnified Party" has the meaning set forth in Section 14.3(a).

"Indemnifying Party" has the meaning set forth in Section 14.3(a).

"Indemnification Notice" has the meaning set forth in Section 14.3(a).

"Indemnity Payment" has the meaning set forth in Section 14.4(a).

"Indication" means a human disease or medical condition which is approved by a Regulatory Authority to be included as a discrete claim (as opposed to a subset of a claim) in the Labeling of a Product based on the results of a Phase III Clinical Trial(s) sufficient to support Regulatory Approval of such claim.

"Infringement Action" has the meaning set forth in Section 12.4(b).

"Infringement Notice" has the meaning set forth in Section 12.4(a).

"Intellectual Property" means all Patents, Know-How, Trademarks, copyrights and copyrightable subject matter (including rights in computer software), rights in databases, compilations and data, and any and all other intellectual property and industrial property rights now known or hereafter recognized in any country throughout the world, whether registered or not, together with all applications and registrations therefor.

"IV Formulation" means a formulation of the Product for intravenous administration.

"Joint Know-How" has the meaning set forth in Section 12.2.

"JSC" has the meaning set forth in Section 2.3(a).

"JSC Member" has the meaning set forth in Section 2.3(b).

"Know-How" means data, results, technology and information of any type whatsoever, in tangible or intangible form, including know-how, knowledge, techniques, practices, methods, processes, discoveries, developments, inventions, specifications, formulations, formulae, designs, trade secrets, information included in regulatory filings or with respect to materials or compositions of matter, including marketing and supply information, software, algorithms, marketing reports and plans, market research, expertise, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, and other study data and procedures.

"Knowledge" means, as applied to a Party, that such Party shall be deemed to have knowledge of a particular fact or other matter to the extent that a reasonably prudent person

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with primary responsibility for the applicable subject matter (whether an officer or employee of such Party) knew or should have known of such fact or other matter.

"Labeling" means any and all labels, labeling, packaging, package inserts and outserts, labels for samples, and promotional materials for any Product in the Field in the Territory.

"License Arbitrator" has the meaning set forth in Section 16.1(c)(i).

"License Terms" has the meaning set forth in Section 16.1(c).

"Losses" has the meaning set forth in Section 14.1.

"Major Market Country" means any of the U.S., EU5 and Japan.

"Manufacture" or "Manufacturing" means all activities related to the manufacturing of any Product, or any ingredient thereof, including producing, manufacturing for clinical use or commercial sale, processing, filling, finishing, labeling, in-process and product testing, release, quality assurance activities related to manufacturing and release, handling and storage, placebos and comparator agents, as applicable, and ongoing stability and regulatory activities related to any of the foregoing.

"Milestone Event" has the meaning set forth in Section 8.2(a).

"Milestone Payment" has the meaning set forth in Section 8.2(a).

"NDA" or "New Drug Application" means a new drug application submitted to the FDA pursuant to 21 C.F.R. §314, seeking permission to market a Product for use in the Field in the U.S.

"Net Sales" means the gross amount invoiced of a Product sold by or on behalf of Takeda, its Affiliates, or its Sublicensees, less the following deductions provided by Takeda, its Affiliates or its Sublicensees to any Third Party, to the extent reasonable and customary and actually allowed and incurred with respect to such sales:

(a) cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local governments;

(b) discounts provided in connection with coupon, voucher or similar patient programs;

(c) credits and allowances actually granted upon damaged goods, rejections, or returns of such Products, including in connection with recalls and the actual amount of any write-offs for bad debt (provided that amounts subsequently recovered will be treated as Net Sales);

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(d) packaging, freight and insurance charges actually allowed or paid for delivery of Products, to the extent actually paid and any customary payments with respect to the Product actually paid to wholesalers or other distributors; and

(e) taxes (other than income or withholding taxes), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Product, including VAT, excise taxes, sales taxes, and that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), that Takeda, its Affiliates or Sublicensees, as applicable, reasonably allocate on a pro rata basis to sales of such Product in accordance with Takeda's, its Affiliates' or Sublicensees' standard policies and procedures consistently applied across all of its products, as applicable, in each case, to the extent non-creditable or refundable.

Sales or other transfers of Products between and among Takeda, any of its Affiliates or any of its Sublicensees which are subsequently resold or to be resold by such Affiliates or Sublicensees shall not be Net Sales, but any subsequent sale or other transfer of such Products to a Person who is not an Affiliate or Sublicensee shall be Net Sales.

For purposes of determining Net Sales, a Product shall be deemed to be sold when recorded by or on behalf of Takeda, its Affiliates or its respective Sublicensees in accordance with IFRS. For clarity, a particular deduction set forth above may only be accounted for once in the calculation of Net Sales and to the extent these deductions are refunded or credited by Third Parties or government agencies, such refunds or credits shall be added back in the calculation of Net Sales. Products transferred to Third Parties in connection with clinical or non-clinical research or trials or as Product samples shall give rise to Net Sales only to the extent that Takeda or any of its Affiliates or Sublicensees invoices or receives amounts therefor. For the avoidance of doubt, as applied for all purposes in this Agreement, Net Sales shall be accounted for in accordance with standard accounting practices, as practiced by Takeda, its Affiliates or its respective Sublicensees in the relevant country in the Territory; provided that such accounting is in accordance with IFRS, as consistently applied in such country in the Territory.

The Net Sales of any Combination Product:

(x) for which the Compound and other active ingredient(s) of such Combination Product are each sold separately by Takeda, or any of its Affiliates or Sublicensees, in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the total sales (as measured by IMS or a similar data vendor) of both the branded and generic Single Active Product divided by the total units (as measured by IMS or a similar data vendor) of both the branded and generic Single Active Product as the only active ingredient, and B is total Net Sales (as measured by IMS or a similar data vendor) of both the branded and generic other active ingredient(s) in the Combination Product divided by the total units (as measured by IMS or a similar data vendor).

(y) for which (i) the Compound is/are sold separately by Takeda or any of its Affiliates or Sublicensees in such country and (ii) the other active ingredient(s) in the Combination

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Product is/are not sold separately by Takeda or any of its Affiliates or Sublicensees in such country, then Net Sales for such Combination Product in such country shall be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/D, where A is the average Net Sales price of the Single Active Product of the Product, as sold separately by Takeda or any of its Affiliates or Sublicensees in such country, and D is the average Net Sales price of the Combination Product as sold separately by Takeda or any of its Affiliates or sublicensees in such country; and

(z) for which neither clause (x) nor clause (y) above is applicable, the Parties shall determine Net Sales for such Combination Product in such country by mutual agreement based on the relative contribution of the Product and the other active ingredient(s) in the Combination Product.

"New York Courts" has the meaning set forth in Section 16.1(b).

"Non-Contracting Party" has the meaning set forth in Section 3.4.

"Non-Controlling Party" has the meaning set forth in Section 12.4(b).

"Non-Prosecuting Party" has the meaning set forth in Section 12.3(c).

"Non-U.S. Competition Filings" has the meaning set forth in Section 10.5(b)(ii).

"Notice Period" has the meaning set forth in Section 15.3.

"Ongoing Trial" means any Clinical Trial for the Product where the first subject has been dosed and for which all activities related to such Clinical Trial has not reached Study Completion.

"Oral Formulation" means a formulation of the Product for oral administration (such as a tablet or capsule).

"Paragraph IV Notice" means (a) a notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) concerning any Product or (b) any substantially similar notice provided under any Applicable Laws outside the U.S.

"Patents" means all patents and patent applications and substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, restorations, patents from post-grant proceedings, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.

"Person" means a limited or general partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization or association, Governmental Authority, or any other entity, or an individual.

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"Phase II Clinical Trial" means a Clinical Trial the principal purpose of which is to make a preliminary determination that a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product's efficacy or dose-response information, in a manner which is consistent with 21 C.F.R. § 312.21(b).

"Phase III Clinical Trial" means a pivotal Clinical Trial or comparable registrational clinical trial with a defined dose or a set of defined doses of a pharmaceutical product designed to determine efficacy and safety of such product for the Indication being studied, in a manner which is consistent with 21 C.F.R. § 312.21(c).

"Post-Marketing Study" shall mean any study conducted with respect to a Product after submission of an application for Regulatory Approval for such Product, whether initiated by a Party or at the request of an applicable Governmental Authority, to delineate additional information about a drug's risks, benefits, and optimal use, including safety surveillance studies, pharmacoeconomic studies, pharmacoepidemiology studies, studies relating to different dosing or schedules of administration, studies of the use of the drug in other patient populations or other stages of the disease, or studies of the use of the drug over a longer period of time. For clarity, Post-Marketing Studies shall not include studies designed to determine the efficacy of a drug for an Indication for which Regulatory Approval has not been granted or studies that are otherwise required to obtain or maintain Regulatory Approval.

"Pricing Approval" means the approval, agreement, determination, or decision from a Regulatory Authority establishing the price for a Product that can be charged to consumers and/or will be reimbursed by Governmental Authorities in a given country within the Territory, as required by Applicable Law in such country prior to the sale of the Product in such country.

"Product" means any Single Active Product or Combination Product.

"Product Complaint" means any written, verbal, or electronic expression of dissatisfaction regarding any Product sold by or on behalf of Takeda or any of its Affiliates or Sublicensees within the Territory, including reports of actual or suspected product tampering, contamination, mislabeling, or inclusion of improper ingredients.

"Product Share" means, with respect to a Product in a country in the Territory, the units (as measured by IMS or a similar data vendor) of a Party's branded version of such Product divided by the sum of the branded Product units plus Generic Product units of such Product in such country, in each case normalized for dosage strength.

"Product Trademark" means, with respect to each Product, any Trademarks used in connection with Commercialization of the Product for use in the Field in the Territory.

"Prosecuting Party" has the meaning set forth in Section 12.3(c).

"Prosecution Activities" has the meaning set forth in Section 12.3(a).

"Public Official" means any Person holding, representing or acting on behalf of a Person holding a legislative, administrative or judicial office, and any Person employed by,

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representing or acting on behalf of a Governmental Authority or enterprise thereof, public international organization, any representative or official of a political party or any candidate for any political office or any official or employee of any state owned or controlled entity.

"Publishing Party" has the meaning set forth in Section 9.4.

"PVA" has the meaning set forth in Section 6.2.

"Recall" has the meaning set forth in Section 6.1.

"Receiving Party" has the meaning set forth in Section 9.1.

"Regulatory Approvals" means, with respect to any Product in a country in the Territory, all approvals (such as an NDA), including any Pricing Approvals, if applicable, necessary for the commercial sale of such Product in the Field in such country in the Territory. Regulatory Approvals shall not include any INDs or any approval required solely for Development or other pre-Commercial activities with respect to any Product.

"Regulatory Approval Milestone" has the meaning set forth in Section 8.2(b)(i).

"Regulatory Authority" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other Governmental Authority in any country in the Territory with authority over the Development or Commercialization of any Product for use in the Field under this Agreement, including the FDA, the EMA and the Japanese Ministry of Health, Labour and Welfare.

"Regulatory Exclusivity" means any exclusive marketing rights or regulatory exclusivity conferred by any Regulatory Authority with respect to a Product (excluding Patents), including rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto outside the U.S.

"Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations, INDs, Regulatory Approvals and other filings and submissions made to, received from or otherwise conducted with a Regulatory Authority that are necessary or reasonably useful in order to Exploit a Product in the Field in the Territory. For the avoidance of doubt, "Regulatory Materials" shall include, with respect to Products, all INDs, Regulatory Approval applications, Regulatory Approvals, Pricing Approvals and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.

"Regulatory Transfer Date" has the meaning set forth in Section 4.9(b).

"Reimbursed Expenses" has the meaning set forth in Section 8.6.

"Restricted Activities" has the meaning set forth in Section 10.6(a).

"Retained Information" has the meaning set forth in Section 15.8(c).

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"Royalties" has the meaning set forth in Section 8.3(a).

"Safety Reasons" means that a Product has caused or based on objective scientific or clinical evidence, is reasonably likely to cause [***] that (when considered in their totality) is reasonably likely: (a) [***]; or (b) if Regulatory Approval has already been obtained, [***].

"SEC" means the U.S. Securities and Exchange Commission.

"Second Submission" has the meaning set forth in Section 16.1(c)(ii).

"Shelving Breach" has the meaning set forth in Section 15.7.

"Single Active Product" means any pharmaceutical product, including all forms, presentations, strengths, doses and formulations (including any method of delivery) containing the Compound as the sole therapeutically active ingredient.

"Study Completion" means completion of the analytical efforts including creation and validation of study data tabulation model data conversion (SDTM), Clinical Data Interchange Standards Consortium analysis data model datasets (CDISC ADaM), and tables, listings and figures in accordance with the pre-specified statistical analysis plan (to be finalized before database lock).

"Subcontractor" has the meaning set forth in Section 3.3.

"Sublicensee" means a Third Party or Affiliate to whom Takeda (or Takeda's sublicensee to the extent permitted hereunder) grants a sublicense under the TBIL Technology to the extent permitted hereunder. For clarity, a "Sublicensee" will include a Third Party to whom Takeda grants rights to distribute any Products for use in the Field in any country in the Territory if such distributor pays Takeda royalties or other amounts based upon the net sales of such Products by such distributor rather than transfer price for such Product supplied by or on behalf of Takeda.

"Takeda FTE Rate" means a rate of $[***] USD per FTE in the first consecutive twelve (12)-month period, such amount to be adjusted on an annual basis by the average of the percentage increases or decreases, if any, in the US CPI-U for such twelve (12)-month period.

"Takeda Indemnitee" has the meaning set forth in Section 14.1.

"Takeda Internal Costs" means, with respect to a particular activity, the product of (a) the total number of FTEs, as determined by the number of Takeda's and its Affiliates' personnel that are conducting such activities and (b) the Takeda FTE Rate.

"Takeda Know-How" means, to the extent Controlled by Takeda or any of its Affiliates at any time during the Term, all Know-How that is necessary or useful to Exploit any Product to the extent permitted hereunder or is actually incorporated, or actually used, by Takeda or its Affiliates in the Exploitation of any Product during the Term. Notwithstanding the foregoing, in no event shall the Takeda Know-How include any Patents.

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"Takeda Patents" means to the extent Controlled by Takeda or any of its Affiliates at any time during the Term, all Patents that Cover any Product, or would otherwise be necessary or useful to Exploit any Product for use in the Field throughout the Territory to the extent permitted hereunder or that Cover any subject matter actually incorporated, or actually used, by Takeda or any of its Affiliates in the Exploitation of any Product during the Term. Notwithstanding the foregoing, in no event shall the Takeda Patents include any Know-How.

"Takeda Proposed Terms" has the meaning set forth in Section 16.1(c)(ii).

"Takeda Technology" means the Takeda Patents, the Takeda Know-How and Takeda's interest in any Joint Know-How.

"Taxes" has the meaning set forth in Section 8.12.

"TBIL Agreements" has the meaning set forth in Section 10.5(f)(v).

"TBIL Indemnitee" has the meaning set forth in Section 14.2.

"TBIL FTE Rate" means a rate of $[***] USD per FTE in the first consecutive twelve (12)-month period, such amount to be adjusted on an annual basis by the average of the percentage increases or decreases, if any, in the US CPI-U for such twelve (12)-month period.

"TBIL Internal Costs" means, with respect to a particular activity, the product of (a) the total number of FTEs, as determined by the number of TBIL's and its Affiliates' personnel that are conducting such activities and (b) the TBIL FTE Rate.

"TBIL Know-How" means to the extent Controlled by TBIL or any of its Affiliates at any time during the Term, all Know-How that is necessary or useful to Exploit any Product to the extent permitted hereunder. Notwithstanding the foregoing, in no event shall the TBIL Know-How include any Patents.

"TBIL Patents" means to the extent Controlled by TBIL or any of its Affiliates at any time during the Term, all Patents that Cover the Products or would otherwise be necessary or useful to Exploit any Product for use in the Field throughout the Territory to the extent permitted hereunder, including those Patents set forth in Exhibit 1.1(b). Notwithstanding the foregoing, in no event shall the TBIL Patents include any Know-How.

"TBIL Proposed Terms" has the meaning set forth in Section 16.1(c)(ii).

"TBIL Technology" means the TBIL Patents, the TBIL Know-How and TBIL's interest in any Joint Know-How.

"Term" has the meaning set forth in Section 15.1.

"Terminated Country" has the meaning set forth in Section 15.8(a)(i).

"Territory" means worldwide.

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"Third Party" means any Person other than TBIL or Takeda or their respective Affiliates.

"Third Party Claim" has the meaning set forth in Section 14.1.

"Third Party Expenses" means out-of-pocket payments made to a Third Party for services and/or goods provided in connection with the activities contemplated under the Development Plan or the Commercialization Plan or otherwise as expressly provided in this Agreement.

"Third Party Fees" has the meaning set forth in Section 15.8(a)(x).

"Third Party Infringement" has the meaning set forth in Section 12.4(a).

"Third Party IP" has the meaning set forth in Section 8.4(a).

"Trademarks" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

"Transfer Plan" has the meaning set forth in Section 4.3(a).

"Transferred Regulatory Materials" has the meaning set forth in Section 4.9(a).

"United States," "US" or "U.S." means the United States of America, including its territories and possessions.

"Upfront Payment" has the meaning set forth in Section 8.1.

"US CPI-U" means the Consumer Price Index for All Urban Consumers: U.S. City Average (all items) published by the U.S. Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).

"Valid Claim" means (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) (i) which has not been revoked or held to be unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which decision no appeal can be further taken or has been taken within the time allowed for appeal, and (ii) which has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a pending Patent application (whether filed before or after the Effective Date), which claim has been pending less than six (6) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued patent (from and after which time the same shall be deemed a Valid Claim subject to subsection (a) above), and which claim was filed and is being prosecuted in good faith and has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

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"Velusetrag" means (a) the chemical compound *N*-{(1*R*,3*r*,5*S*)-8-[(2*R*)-2-hydroxy-3-(*N*-methylmethanesulfonamido)propyl]-8-azabicyclo[3.2.1]octan-3-yl}-2-oxo-1-(propan-2-yl)-1,2-dihydroquinoline-3-carboxamide having the chemical structure set forth in Exhibit 1.1(c) and (b) [***].

"Withholding Party" has the meaning in Section 8.12(a).

ARTICLE II
COLLABORATION AND GOVERNANCE

2.1 Scope of Collaboration. Subject to the terms and conditions of this Agreement, the Parties shall cooperate in good faith to Develop and Commercialize the Products for use in the Field in the Territory (the "Collaboration").

2.2 Governance, Generally. The Parties hereby acknowledge and agree that the Committees and the procedures set forth in this Article II have been established in order to manage, oversee and coordinate the Collaboration under this Agreement. When making a decision or otherwise resolving a dispute under this Article II, each Party shall, acting in good faith and a manner consistent with its respective rights and obligations under this Agreement, attempt to reach consensus.

2.3 Joint Steering Committee.

(a) Purpose: Within thirty (30) days of the Effective Date, the Parties shall establish a joint steering committee (the "JSC"), which shall have the following responsibilities:

(i) providing a forum for the overall coordination, communication, and oversight of the Collaboration;

(ii) managing, reviewing and discussing the overall strategy for Developing and Commercializing the Products hereunder;

(iii) reviewing and approving any Development Plans and any material modifications thereof or material amendments thereto;

(iv) reviewing and approving the plans with respect to a CVOT and any material modifications thereof and material amendments thereto; provided, that, such review and approval right would only apply to the extent TBIL is reimbursing Takeda's expenses related to a CVOT pursuant to Section 8.7;

(v) reviewing and commenting on any Commercialization Plans and any material modifications thereof or material amendments thereto;

(vi) life cycle management of the Products;

(vii) establish any working teams or subcommittees;

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(viii) provide a forum for the Parties to discuss and attempt to resolve disputes referred to the JSC; and

(ix) such other responsibilities assigned to the JSC by this Agreement as the Parties may mutually agree to further the purposes of this Agreement.

(b) Membership. The JSC shall initially consist of six (6) members who have appropriate seniority and expertise (each, a "JSC Member"), three (3) of whom shall be designated by Takeda and three (3) of whom shall be designated by TBIL.

(c) JSC Meetings. The Parties shall endeavor to have the JSC's first meeting within forty-five (45) days after its establishment. Thereafter, except as otherwise agreed by the Parties, the JSC shall hold at least four (4) meetings per Calendar Year spaced at reasonably regular intervals (as agreed upon by the JSC). A JSC meeting shall not be effective unless at least half of each Party's JSC's Members is present. JSC meetings may occur either (i) in person at either Party's facilities or at such locations as the Parties otherwise agree, or (ii) by audio or video teleconference; provided that unless the Parties mutually agree otherwise, at least one JSC meeting will be held in person each Calendar Year.

(d) Decision-Making. The JSC shall be responsible for making decisions within the scope of its decision-making authority as set forth in this Agreement (including Section 2.3(a)), which decisions shall be made by consensus, with each Party having, collectively, among its respective JSC Members, one (1) vote, subject to Section 2.6.

(e) Meetings After First Commercial Sale. Subject to Section 2.7(e), upon First Commercial Sale of a Product in the U.S or EU5, the Parties will discuss the frequency of JSC meetings. Thereafter, unless mutually agreed by the Parties, the JSC shall meet at least once every six (6) months.

2.4 Other Working Groups. From time to time, the JSC may establish and delegate duties to other working groups to oversee particular projects or activities which are within the authority of the JSC as provided in Section 2.3 (which working groups may be established on an ad hoc basis for a specific project or such other basis as the JSC determines); provided that in no event shall such duties and responsibilities exceed the power and authority assigned to the JSC hereunder and further provided that the JSC may not delegate to any working group the authority to make decisions with respect to any matter for which it has decision-making authority. Each such working group shall be constituted as agreed upon by the Parties and shall operate as the JSC determines.

2.5 Alliance Managers. Promptly following the Effective Date (but in no event later than within fifteen (15) Business Days thereof), each Party shall designate an Alliance Manager, which may be changed by such Party from time to time upon written notice to the other Party.

2.6 Committee Dispute Resolution Procedures.

(a) Working Group Disputes. If, for any reason any working group (as established in accordance with Section 2.4) is unable to reach a consensus regarding a matter within the scope of its authority within [***] days of such matter being first referred to such

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working group by either Party or any of its respective members, then the matter shall be referred, in writing, by either Party to the JSC for determination.

(b) Referral to Officers. If, for any reason, the JSC is unable to reach a consensus regarding a matter within the scope of its decision-making authority (including matters that are referred to the JSC in accordance with Section 2.6(a)) within [***] days of such matter being first referred to the JSC by either Party or any of its respective members, then the matter shall be referred to the Chief Executive Officer of Takeda or other appropriate senior executive officer designated by Takeda, and the Chief Executive Officer of the ultimate parent company of TBIL or other appropriate senior executive officer designated by TBIL (collectively, the "Officers"), with decision-making authority for the applicable matter for resolution by consensus.

(c) Resolution. If, for any reason, the Officers (or such other senior executive officer(s) described in Section 2.6(b), as applicable) are unable to resolve, in writing and by consensus, a matter referred to them under Section 2.6(b) within [***] days of such matter being first referred them, then Takeda's Officer shall have the final decision-making authority on such matter, and the course of action determined by Takeda's Officer shall be undertaken, except that Takeda's Officer shall not use such final decision-making authority (including by amending the Development Plan) in a manner that would materially increase or accelerate any financial obligation or resource commitment (including the total number of FTEs) of TBIL, or otherwise be inconsistent with this Agreement.

2.7 General Principles.

(a) Each Committee shall not have any authority beyond the specific responsibilities set forth in this Agreement for such Committee. The Parties acknowledge and agree that none of the JSC, any working groups, or the Officers have the power to amend, modify or waive compliance under any of the terms or conditions of this Agreement.

(b) Each of Takeda and TBIL may replace any of its Committee members at any time, provided that prior written notice or prior notice by email, to the other Party shall be required before any such member is replaced. A Party may designate a substitute to temporarily attend and perform the functions of such Party's Committee member at any Committee meeting. Each Party shall be permitted to appoint as Committee members individuals who are not employees of such Party or any of its Affiliates; provided that the other Party grants prior written consent (which consent may be granted or denied at such other Party's sole discretion). Each Committee may change the number of its members upon mutual agreement of the Parties; provided that such agreement shall be in writing or by email, and unless otherwise agreed by the Parties, the JSC shall always have equal representation of the Parties thereon. Each Party may invite individuals who are not members of such Committee to attend Committee meetings; provided that prior written notice or prior notice by email shall be required before the applicable meeting; and provided, further, that any invitee who is not an employee or designee of such Party (nor any of its Affiliates) shall only have the right to attend such Committee meeting with the prior written or email consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed) and under a written obligation of confidentiality and non-use consistent

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with the provisions set forth in Article IX. Notwithstanding the foregoing, the Alliance Managers may attend Committee meetings without such notice.

(c) The JSC shall be chaired by a Takeda JSC Member. The chairperson shall be responsible for calling and leading meetings and preparing and circulating an agenda for any upcoming meeting; provided that such agenda shall include items proposed by either Party no less than five (5) Business Days prior to such meeting. The Alliance Managers (or their respective designees) shall be responsible for preparing reasonably detailed written minutes of the JSC's meetings that reflect all material decisions made at such meetings. For clarity, the chairperson shall have no additional powers or rights beyond those held by the other JSC members. The Alliance Managers (or their respective designees) shall send draft meeting minutes to each member of the JSC for review and approval within [***] Business Days after the applicable JSC meeting, and such minutes shall be deemed approved unless [***] JSC members objects to the accuracy of the minutes within [***] Business Days of receipt.

(d) In the event that either Party believes that the time periods set forth in this Article II would hinder or delay any Development activities or otherwise materially adversely affect the Products or patient safety or violate Applicable Laws hereunder, the Parties shall, upon mutual agreement, reduce such time periods as reasonably necessary to prevent such hindrance or delay. Notwithstanding anything to the contrary in this Agreement, in the event a matter is in dispute at any Committee, Takeda shall have the right to exercise its final decision-making authority under Section 2.6(c) at any time (i.e., without the escalation procedure set forth in Section 2.6(a) or Section 2.6(b)) after notifying the JSC and giving TBIL a reasonable opportunity, based on the circumstances, but in no event greater than [***] Business Days, to respond, if in Takeda's reasonable judgment, compliance with the escalation procedures set forth in Section 2.6(a) and 2.6(b) (including as modified by the preceding sentence) would result in a violation of any Applicable Law or would have a material adverse effect on patient safety; provided that such right shall not be exercised in a manner that overrides any express provision of this Agreement (other than Sections 2.6(a) and (b)).

(e) Each Committee shall continue to exist until the first to occur of (i) the Parties mutually agreeing to dissolve it or (ii) TBIL providing Takeda written notice of its intention to dissolve and no longer participate in such Committee. In the event that any Committee (other than the JSC) is dissolved pursuant to the foregoing sentence, TBIL's powers and responsibilities within such Committee shall automatically be assumed by the JSC (or Takeda as set forth in the following sentence if the JSC is also dissolved). In the event the JSC is dissolved, TBIL's powers and responsibilities within the JSC shall automatically be assumed by Takeda and Takeda shall have the right to make all decisions previously under the decision-making authority of the JSC.

(f) Each Party shall bear its own expenses in connection with its activities under this Article II, including the attendance and participation at any of the Committee meetings, including travel expenses, and the Parties shall share equally any joint expenses (such as conference room rental and the like).

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ARTICLE III
LICENSE GRANTS

3.1 License Grants to Takeda and Sublicensing Rights.

(a) License Grant. Subject to the terms and conditions of this Agreement, TBIL and its Affiliates hereby grant to Takeda a non-transferable (except as permitted by Section 17.8), sublicenseable (to the extent permitted in Section 3.1(b)), exclusive (including as to TBIL and its Affiliates) (subject to Section 3.5) license under the TBIL Technology solely to Exploit the Compound and the Products for use in the Field throughout the Territory.

(b) Sublicensing Rights of Takeda. Subject to Section 3.4, Takeda shall have the right to grant sublicenses (through multiple tiers) under the license granted to Takeda pursuant to Section 3.1(a) to (i) its Affiliates; (ii) any Third Party with written notice to TBIL anywhere in the Territory outside any Major Market Country; or (iii) subject to TBIL's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), any Third Party in any Major Market Country.

3.2 License Grants to TBIL.

(a) License Grant. Subject to the terms and conditions of this Agreement, Takeda and its Affiliates hereby grant to TBIL and its Affiliates a non-transferable (except as permitted by Section 17.8), non-sublicenseable, non-exclusive license under the Takeda Technology solely to the extent necessary for TBIL to perform its obligations under this Agreement and subject to the terms hereof.

3.3 Subcontracting. Each Party shall be permitted to use Third Party subcontractors to perform activities for which such Party is responsible (each, a "Subcontractor"), subject to the terms hereof (including Section 3.4); provided that TBIL's use of a Subcontractor shall be limited to performance of its obligations under Article VII, unless otherwise agreed by the JSC. TBIL shall obtain Takeda's prior written consent prior to engaging any such Subcontractor (which consent shall not be unreasonably withheld, conditioned or delayed).

3.4 Sublicensing and Subcontracting Conditions. Each sublicense that Takeda grants to a Sublicensee (or such Sublicensee grants to another Sublicensee) or subcontract that a Party grants to a Subcontractor (the "Contracting Party") shall be granted pursuant to an agreement which (a) is subject to, and consistent with, the terms and conditions of this Agreement, and (b) includes provisions at least as protective of the other Party (the "Non-Contracting Party") as the provisions of this Agreement, and (c) if the Sublicensee or Subcontractor (as applicable) is a Third Party, is in writing. For clarity, the granting of a sublicense or subcontract hereunder shall not relieve the Contracting Party of any of its obligations hereunder and the Contracting Party shall cause its Sublicensees and Subcontractors to comply, and shall remain responsible for its Sublicensees' and Subcontractors' compliance, with all of the terms hereof applicable to the Non-Contracting Party. In the case of any sublicense (but not subcontract), Takeda shall provide TBIL with a true and complete copy of each such written agreement (and any amendment thereto) entered into with a Third Party no later than [***] days after each such agreement (or any amendment thereto) has been executed; provided that Takeda shall have the right to redact commercially sensitive information from such copies, provided that Takeda shall not redact any information that pertains to the compliance of such written agreement with this Section 3.4. For

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clarity, information regarding the scope of the license grants, territory and/or term of each such sublicense shall not be considered commercially sensitive (and shall not be redacted).

3.5 Retained Rights. Notwithstanding Section 3.1, TBIL expressly reserves all rights in, to, and under the TBIL Technology solely to the extent necessary to perform its obligations under this Agreement.

3.6 No Implied License. Except as expressly provided in this Article III or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have granted to the other Party or its Affiliates, any license or other rights, express or implied, under such Party's Intellectual Property, whether by implication, estoppel or otherwise.

ARTICLE IV
DEVELOPMENT ACTIVITIES

4.1 Overview of Development. Subject to the terms and conditions of this Agreement, the Parties intend to collaborate to Develop the Products for use in the Field in the Territory under the general direction and oversight of the JSC or such other applicable Committee that is designated such responsibility.

4.2 Development Plan.

(a) General. The Parties shall use Commercially Reasonable Efforts to Develop the Products in accordance with a comprehensive plan for such Development (the "Development Plan") as described in Section 4.2(c). Takeda shall be responsible for those activities set forth in the Development Plan and TBIL shall perform no Development activities unless both expressly set forth in the Development Plan and agreed upon in writing by TBIL (including documentation in the JSC minutes) in its sole discretion. The Development Plan shall encompass all Products under Development by Takeda, its Affiliates, its Sublicensees and its Subcontractors under this Agreement.

(b) Development Plan. Within [***] days following the first meeting of the JSC, Takeda shall prepare and submit to the JSC for review and approval the Development Plan.

(c) Development Plan Contents. The Development Plan shall set forth in reasonable detail the objectives and planned tasks for Development of at least one (1) Product intended to support its Regulatory Approval in the Major Market Countries. Without limiting the foregoing, the Development Plan shall include for such Development:

(i) any material Development activities (including Clinical Trials, research or manufacturing activities) that are to be conducted by or on behalf of each Party, its Affiliates and its Sublicensees and the estimated timeline for completing each such Development activity;

(ii) planned regulatory strategy for obtaining Regulatory Approval for at least one (1) Product in the Major Market Countries; and

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(iii) an estimated annual budget of Third Party Expenses that are expected to be incurred under the Development Plan during the period for which the applicable Development Plan relates (the "Development Budget").

4.3 Transfer of Technology and Responsibilities.

(a) Transfer Plan. As soon as practicable after the Effective Date, but in no event later than [***], the Parties shall (i) develop and agree on a transition plan (the "Transfer Plan") under which, in accordance with the terms hereof, TBIL will transfer to Takeda all TBIL Know-How that exists or is anticipated to exist at the time TBIL completes its activities under the Transfer Plan and (ii) use reasonable efforts to complete the activities thereunder. For clarity, the Parties acknowledge that the activities under the Transfer Plan are separate from the activities contemplated under the Development Plan and that those activities under the Transfer Plan may continue beyond the Regulatory Transfer Date. TBIL shall use Commercially Reasonable Efforts to conduct the activities set forth in the Transfer Plan, and Takeda shall cooperate in good faith to support and provide assistance to TBIL in connection therewith. In the event that, following completion of the activities set forth in the Transfer Plan, at any time during the Term, Takeda believes that it has not received certain TBIL Know-How described in the Transfer Plan, Takeda shall provide written notice to TBIL and TBIL shall promptly transfer such TBIL Know-How to Takeda. During the Term, periodically upon Takeda's reasonable written request, TBIL shall transfer to Takeda all TBIL Know-How then existing and that has not been previously transferred to Takeda.

(b) Transfer Plan Expenses. Except as expressly set forth in Section 7.2, each Party shall be responsible for those internal expenses incurred in furtherance of the Transfer Plan. Takeda shall reimburse TBIL for its Third Party Expenses reasonably incurred in furtherance of the Transfer Plan (if any). Takeda shall reimburse TBIL for such Third Party Expenses in accordance with Section 8.6.

4.4 Development Updates and Development Plan Amendments.

(a) Development Updates. Each Party (to the extent applicable with respect to TBIL) shall submit periodic reports to the JSC on a semi-annual basis, describing its activities under the Development Plan, together with all results and data generated therefrom during the reporting period.

(b) Development Plan Amendments. From time to time as necessary after the approval of the first Development Plan, Takeda shall prepare and submit for approval to the JSC, any updates to the Development Plan. Once approved by the JSC, each amended Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval.

4.5 TBIL Approval of Development of Oral Formulation. Takeda and its Affiliates and its and their respective Sublicensees [***], provided, that TBIL may only [***] (a) [***] or (b) TBIL or its current licensee, pursuant to the [***].

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4.6 Material Changes to Development Timelines. In the event that either Party reasonably believes that there will be a material delay in the Development timeline as compared to the Development timeline in the then-current Development Plan, such Party shall, as soon as reasonably practicable after such Party or any of its Affiliates becomes aware of such delay or at the next regularly scheduled meeting of the JSC, whichever is sooner, notify the other Party in writing and, if the other Party reasonably requests, the JSC shall promptly discuss the strategy to mitigate the effects of, and otherwise limit, such delay.

4.7 Development Expenses. Except as set forth in Section 8.7, Takeda shall have sole responsibility for all expenses incurred in connection with Development of the Products for use in the Field throughout the Territory after the Effective Date. Takeda shall reimburse TBIL for the TBIL Internal Costs and TBIL's and its Affiliates' Third Party Expenses incurred in furtherance of the Development Plan. Takeda shall reimburse TBIL in accordance with Section 8.6. For the avoidance of doubt, Takeda shall have no obligation to reimburse TBIL's FTE costs related to TBIL's participation on any Committee or its participation in connection with the review of any Regulatory Materials or attendance at any meetings with Regulatory Authorities.

4.8 Development Records. Each Party shall maintain current and accurate records of all Development activities conducted by or on behalf of such Party, its Affiliates or, in the case of Takeda, its Sublicensees in connection with this Agreement, and all data and other information collected or resulting from such work. Such records shall properly reflect all work done and results achieved in the performance of the Development activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical and preclinical studies and Clinical Trials to be conducted pursuant to the Development Plan (to the extent applicable with respect to TBIL) in formal written study reports according to applicable national and international (e.g., ICH, GCP, and GLP) guidelines.

4.9 Regulatory. The regulatory strategy for the Products for use in the Field within the Territory shall be consistent with the overall objective of obtaining Regulatory Approval for the Products in accordance with the Development Plan.

(a) Transfer of Regulatory Filings and Regulatory Responsibilities. Within [***] days of the Effective Date or such other time as otherwise agreed upon by the Parties, TBIL shall perform those reasonable activities that are required to assign to Takeda each IND filed by or on behalf of TBIL for the Products, and within [***] days of the Effective Date, TBIL shall provide Takeda with copies (which may be electronic unless otherwise required by Applicable Laws) of all other Regulatory Materials that support such IND(s) or otherwise pertain to such Products, including: (i) all data contained therein and all supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (ii) other documentation or Know-How reasonably necessary or useful in order to Exploit such Product, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files, Manufacturing records, CMC materials and master files (the "Transferred Regulatory Materials"). Upon Takeda's reasonable request, TBIL shall transfer to Takeda all data, information and other materials underlying or supporting such Transferred Regulatory Materials with respect to each Product.

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(b) Ownership of Regulatory Approvals. Unless otherwise agreed to by the Parties, after TBIL completes transfer to Takeda of the Transferred Regulatory Materials with respect to the Products, Takeda shall own, and hold in its name, the IND and all other Regulatory Materials (including all Regulatory Approvals) for such Products with respect to the Field within the Territory. The date upon which TBIL transfers to Takeda the ownership of the IND Controlled by TBIL for the Products (and any applications therefor) shall be deemed the "Regulatory Transfer Date".

(c) Regulatory Activities and Cooperation. Unless otherwise agreed upon by the Parties, after the Regulatory Transfer Date, Takeda shall be the lead party for all regulatory-related activities with respect to such Products and TBIL shall not communicate or correspond with any Regulatory Authority with respect to such Products without the prior written consent of Takeda unless such communication or correspondence is required to comply with Applicable Laws, in which case TBIL shall, to the extent practicable, notify Takeda and obtain Takeda's written consent prior to engaging in such communication or submitting such correspondence; provided that, upon TBIL's request, Takeda shall: (i) provide TBIL with drafts of all material Regulatory Materials reasonably in advance of submission to a Regulatory Authority for TBIL's review and comment and reasonably consider incorporating TBIL's reasonable comments in connection therewith, (ii) provide TBIL with a copy, in electronic form if reasonably practicable, of all material Regulatory Materials submitted to or received from a Regulatory Authority, promptly, but in no event later than [***] Business Days after receipt or submission thereof, and (iii) notify TBIL reasonably prior to any material meetings and material conferences related to the Products with Regulatory Authorities and unless precluded by Applicable Law, upon TBIL's request, TBIL may attend and observe (and, upon Takeda's request or written consent, which may be withheld or granted at Takeda's sole discretion, participate in) such meetings; provided that, unless otherwise agreed to by Takeda, no more than [***] of TBIL's employees or its designees may attend a meeting with the FDA and no more than [***] of TBIL's employees or its designees may attend a meeting with any other Regulatory Authority, and (iv) upon TBIL's request, provide TBIL with all reports and minutes from all such material meetings and conferences.

4.10 Clinical Trial Transparency. Both Parties agree to collaborate to maintain compliance with all Applicable Laws related to clinical trial transparency, as well as any industry guidelines/codes of conduct, or other obligations that may apply to the sponsor of any Clinical Trial and/or the owner of any Regulatory Approval hereunder. The Parties shall cooperate to maintain clinical trial transparency consistent with the sponsor's clinical trial registration, summary result, and data sharing transparency policies and will support disclosure of information as needed based on the needs of the sponsor of the study or the Regulatory Approval holder hereunder. Each Party agrees to register any Clinical Trials conducted by or on behalf of such Party, or any of its Affiliates or in the case of Takeda, its Sublicensees, under an IND in connection with this Agreement in any clinical trial registry (e.g., clinicaltrials.gov) as required by Applicable Laws; provided that each Party shall use reasonable efforts to inform the other Party prior to posting the results of any such Clinical Trial on any clinical trial registry (e.g., clinicaltrials.gov). Subject to the foregoing obligation to inform TBIL, TBIL further agrees to allow Takeda to post the clinical trial results of such Clinical Trials conducted by or on behalf of TBIL and its Affiliates and to link the registry to the clinical results of all studies that are the basis for the efficacy claims for the Product in the Territory, and the results of any additional

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studies that are conducted after filing for or obtaining Regulatory Approval that provide additional information that is relevant to the use of Products in the Field in the Territory. Takeda shall be responsible for registering in the appropriate clinical trial registry and posting the results of all Clinical Trials, Post-Marketing Studies or other studies, in each case, performed by or on behalf of Takeda, its Affiliates and its Sublicensees for Products in the Field as required by Applicable Laws.

ARTICLE V
COMMERCIALIZATION

5.1 Overview of Commercialization.

(a) General Objectives. Subject to the terms of this Agreement, Takeda shall use Commercially Reasonable Efforts to Commercialize at least one (1) Product for use in the Field in the Territory.

5.2 Commercialization Plan

(a) General. Takeda shall Commercialize the Product hereunder in accordance with a reasonably detailed plan for such Commercialization (each, a "Commercialization Plan"). The Commercialization Plan shall encompass all Products to be Commercialized by Takeda, its Affiliates, its Sublicensees and its Subcontractors under this Agreement.

(b) Commercialization Plan. At least [***] months prior to the first anticipated Regulatory Approval of a Product in a Major Market Country, the JSC shall commence discussions regarding the Commercialization strategy with respect to such Product. Takeda shall submit to the JSC for its review, discussion and comment, an initial draft Commercialization Plan for each Product approximately [***] months prior to the first anticipated Regulatory Approval in a Major Market Country (the date for which shall be determined by the JSC). Following the JSC's timely review, discussion, and comment (which Takeda shall reasonably consider in good faith), Takeda shall finalize the Commercialization Plan and provide a copy thereof to the JSC. Takeda shall be responsible for those activities set forth in the Commercialization Plan and except as set forth in Section 5.6, TBIL shall perform no Commercialization activities unless both expressly set forth in the Commercialization Plan and agreed upon in writing by TBIL in its sole discretion.

(c) Contents. The Commercialization Plan shall include for such Commercialization:

(i) high-level plan for pre-launch, launch and subsequent Commercialization activities, including a conceptual description of any promotional campaigns (in accordance with Section 5.6);

(ii) any Post-Marketing Studies; and

(iii) estimated market and sales forecasts for Major Market Countries.

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5.3 Commercialization Updates; Amendments to Commercialization Plan.

(b) Beginning [***] days before the expected First Commercial Sale of any Product in any country in the Territory, Takeda will provide the JSC with updates, at each JSC meeting, of the material Commercialization activities conducted for the Products throughout the Territory.

(c) On or before [***] of each year during the Term (unless the Parties otherwise agree in writing), Takeda shall prepare and submit to the JSC for its review, discussion, and comment, any updates to the Commercialization Plan. Following the JSC's review, discussion, and comment (which Takeda shall reasonably consider in good faith), Takeda shall finalize the Commercialization Plan and such amended Commercialization Plan shall become effective and supersede the previous Commercialization Plan as of the date of such finalization.

5.4 Commercialization Expenses. Except as set forth in Section 8.7, Takeda shall have sole responsibility for its expenses incurred in connection with Commercialization of the Products for use in the Field throughout the Territory under this Agreement. Takeda shall reimburse TBIL for the TBIL Internal Costs and TBIL's and its Affiliates' Third Party Expenses incurred in furtherance of the Commercialization Plan, in each case, solely with respect to those TBIL Internal Costs and Third Party Expenses incurred in accordance with the Commercialization Plan, and with respect to the TBIL Internal Costs, solely for those specific activities conducted by employees within the functional areas identified in the Commercialization Plan.

5.5 Bundling. Takeda shall not, and shall ensure that its Affiliates and Sublicensees do not, bundle or include any Product as part of any multiple product offering or discount or price in a manner that disadvantages such Product in order to primarily benefit sales or prices of other products.

5.6 TBIL U.S. Co-Promote. No later than [***] months prior to a Product's anticipated First Commercial Sale in the U.S., TBIL may request, in writing, that Takeda grant TBIL the right to co-promote such Product in the U.S. ("Co-Promote"). At Takeda's sole discretion, but in any event, within [***] days of TBIL's written request, Takeda may agree to grant TBIL the right to Co-Promote such Product in the U.S. If Takeda grants TBIL the right to Co-Promote in the U.S., the Parties will promptly negotiate and enter into a separate co-promote agreement for the Commercialization of such Product in the Field in the U.S. by Takeda and TBIL, on mutually agreeable terms as to the manner of such Co-Promote, and the JSC will promptly amend the Commercialization Plan to address the transition of promotional activities from Takeda to both Parties. For the avoidance of doubt, Takeda, at its sole discretion, will determine (i) whether to grant TBIL the right to Co-Promote and if granted, (ii) the promotional activities that TBIL may engage in with respect to such right.

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ARTICLE VI
RECALLS AND OTHER CORRECTIVE ACTIONS AND RELATED MATTERS

6.1 Recalls and Other Corrective Actions. Prior to the Regulatory Transfer Date, decisions with respect to any recall, market withdrawal, or other corrective action related to such Product for use in the Field in the Territory (each, a "Recall") shall be made by TBIL, in consultation with the JSC, and all expenses of such Recall shall be the responsibility of TBIL. In the event that Takeda believes that a Recall of a particular Product may be required prior to the Regulatory Transfer Date, Takeda shall promptly notify TBIL and TBIL shall take such notice into consideration and decide whether such Recall is required. After the Regulatory Transfer Date, decisions with respect to any Recall of such Product shall be made by Takeda, at its sole discretion, and all expenses of such Recall shall be the responsibility of Takeda. In the event that TBIL believes that a Recall may be required, TBIL shall promptly notify Takeda and Takeda shall take such notice into consideration and decide whether such Recall is required. Prior to the Regulatory Transfer Date, the Parties shall jointly determine, and after the Regulatory Transfer Date, Takeda shall determine in its sole discretion, acting reasonably and in good faith and without inappropriately denigrating the Product or the Parties, any actions taken or public statements made in connection with any Recall of such Product and TBIL shall, upon Takeda's reasonable written request, cooperate in such actions.

6.2 Adverse Event Reporting and Safety Data Exchange.

(a) Unless otherwise agreed by the Parties, the specific details regarding the management of safety information including adverse events reports related to the Development and the Commercialization of the Products in the Territory will be delineated in a separate global pharmacovigilance agreement (the "PVA") that shall be agreed to by the Parties as soon as reasonably practicable after the Effective Date. Following execution of the PVA, in the event of an express conflict between this Section 6.2 and the PVA, the terms and conditions of the PVA shall control.

(b) Prior to the Effective Date, TBIL shall have established a global safety database. Prior to the Regulatory Transfer Date, TBIL shall, to the extent required by Applicable Laws, be responsible for monitoring all clinical experiences, maintaining such global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Territory with respect to the Product, including annual safety reports. In accordance with the Transfer Plan, TBIL shall transfer to Takeda the global safety database for the Product to Takeda. At the time of the transfer, TBIL shall confirm in writing that all safety data related to the Product is accurately reflected in the global safety database then-existing and being maintained by TBIL. After the Regulatory Transfer Date, Takeda will assume responsibility for monitoring all clinical experiences, maintaining the global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Territory with respect to the Product, including annual reports, and shall carry out such responsibility in compliance with all Applicable Laws during the remainder of the Term. Until such time as the global safety database for a Product is transferred to Takeda hereunder and thereafter in the event TBIL receives any safety updates with respect to such Product, TBIL shall prepare and provide to Takeda on a timely basis any safety updates received by or on behalf of TBIL or any of its Affiliates and/or Sublicensees; provided that in no case shall the exchange of information related to adverse events occur later than [***] days for any fatality and/or life-threatening safety event,

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[***] days for other related serious adverse events, and [***] days for other, non-serious adverse events.

6.3 Notifications of Regulatory Events.

(a) (i) Prior to the Regulatory Transfer Date, TBIL shall, and (ii) after the Regulatory Transfer Date, Takeda shall, without limiting any other term or condition hereof, notify the JSC, as soon as reasonably practicable, of any action by, or notice or other information that such Party or any of its Affiliates receives (directly or indirectly) from, any Third Party (including any Governmental Authority), which: (1) considered in light of all other information related to the Product, raises any material concerns regarding the safety of the Product; (2) is reasonably likely to lead to a Recall or clinical hold with respect to such Product; or (3) constitutes a notice of an investigation or formal inquiry by any Regulatory Authority regarding such Product.

(b) Without limiting Section 6.3(a) or any other term or condition hereof, (i) before the Regulatory Transfer Date, TBIL shall, and (ii) after the Regulatory Transfer Date, Takeda shall: notify the other Party if such Party or any of its Affiliates learns of (i) non-routine Governmental Authority inspections of any facilities related to the Products (provided that, in no event shall such notice be provided less than [***] hours before such inspection); (ii) receipt of a warning letter issued by a Regulatory Authority; (iii) receipt of Product Complaints related to actual or suspected Product tampering, contamination, or mix-up (e.g., wrong ingredients); or (iv) initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction, in each case of the foregoing subsections (ii), (iii) and (iv), within [***] Business Days thereof.

6.4 Product Complaints. Prior to the Regulatory Transfer Date, TBIL shall be responsible for managing Product Complaints and for formulating and implementing any related strategies and risk management plans and Product Complaint reporting in all countries within the Territory in which such Product is being Developed. After the Regulatory Transfer Date, Takeda shall be responsible for managing Product Complaints and for formulating and implementing any related strategies and risk management plans and Product Complaint reporting in all countries within the Territory in which such Product is being Developed or Commercialized.

6.5 Medical and Consumer Inquiries. Prior to the Regulatory Transfer Date, TBIL shall be responsible for, and, after the Regulatory Transfer Date, Takeda shall be responsible for, responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding the Product in the Field in the Territory. Prior to the Regulatory Transfer Date, if Takeda receives questions related to such Product, and after the Regulatory Transfer Date, if TBIL receives questions related to such Product, Takeda and TBIL, respectively shall, promptly (but in no event later than [***] Business Days from the receipt of such questions) refer such questions to the other Party without responding to such questions itself, and such other Party shall be responsible for responding thereto.

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6.6 Regulatory Inspection or Audit.

(a) If a Regulatory Authority desires to conduct an inspection or audit of TBIL (or any of its Subcontractors, including any contract manufacturer) with regard to a Product in a country in the Territory in regard to any activities conducted by or on behalf of TBIL under this Agreement, including the Development Plan, and/or the Commercialization Plan and/or Transfer Plan, to the extent permitted by TBIL's Third Party agreements relating to such activities (unless such restrictions relate to confidentiality terms which can be satisfied by agreement to customary terms of confidentiality running in favor of such Third Party by Takeda), TBIL shall inform Takeda of such proposed inspection or audit in writing promptly, and not later than [***] Business Days prior to such inspection or audit, to the extent practicable, and shall allow, to the extent permitted under Applicable Law, a representative of Takeda to be present during the portions of such inspection or audit to the extent related to Development or Commercialization of a Product under this Agreement (including related Manufacturing activities). Following receipt of the inspection or audit observations of such Regulatory Authority with respect thereto (a copy of which TBIL will promptly provide to Takeda, to the extent permitted by TBIL's Third Party agreements relating to such activities (unless such restrictions relate to confidentiality terms, in which case, TBIL will use reasonable efforts to obtain such Third Party's consent to disclose such inspection or audit observations to Takeda)), TBIL will also prepare any appropriate responses after reasonably considering and incorporating (to the extent not in violation with Applicable Laws) Takeda's reasonable comments thereto.

(b) If a Regulatory Authority conducts an inspection or audit of Takeda or any of its Affiliates or Subcontractors, which are contract manufacturers, regarding any activities related to the Product conducted by or on behalf of Takeda or its Affiliates under this Agreement, including the Development Plan and/or the Commercialization Plan, then Takeda will provide TBIL, to the extent permitted by Takeda's Third Party agreements relating to such activities (unless such restrictions relate to confidentiality terms, in which case, Takeda will use reasonable efforts to obtain such Third Party's consent to disclose such verbal or written summary to TBIL)], as soon as reasonably practicable, but in no event later than [***] Business Days, with a verbal and written summary of (i) the inspection or audit observations of the Regulatory Authority and (ii) Takeda's response to such Regulatory Authority. Upon termination of this Agreement pursuant to Section 15.2 by mutual written agreement, by TBIL pursuant to Section 15.3, Section 15.4, or Section 15.7 for Takeda's material breach, bankruptcy or Shelving Breach, respectively, or by Takeda pursuant to Section 15.5 or Section 15.6, for convenience or Safety Reasons, respectively, then Takeda will provide TBIL to the extent permitted by Takeda's Third Party agreements relating to such activities (unless such restrictions relate to confidentiality terms, in which case, Takeda will use reasonable efforts to obtain such Third Party's consent to disclose such inspection or audit observations to TBIL), as soon as reasonably practicable, but in any event within [***] Business Days, with a copy of (i) the inspection or audit observations of the Regulatory Authority with respect thereto and (ii) any written response to such Regulatory Authority.

6.7 Audits. Takeda shall have the right to conduct inspections and audits of the facilities of TBIL or of its Affiliates or Subcontractors involved in the Development and/or Commercialization of Products (including related Manufacturing activities) for use in the Field pursuant to this Agreement at reasonable times and on reasonable prior written notice to confirm compliance with the terms hereof.

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ARTICLE VII
MANUFACTURING AND SUPPLY

7.1 Transfer of Manufacturing.

(a) Transfer of Manufacturing Activities. As part of the activities under the Transfer Plan and specifically but without limiting Section 4.3, each Party shall use Commercially Reasonable Efforts to conduct the activities set forth in the Transfer Plan to effectuate the transfer of the Manufacturing of the Products to Takeda according to the timeline set forth in the Transfer Plan. The Transfer Plan may include, subject to the Parties' written agreement, any interim supply of the Compound and/or Products by or on behalf of TBIL or its Affiliates to Takeda.

(b) Transfer of Inventory. In connection with such transfer, in the event that TBIL has any inventory of the Compound or the Product or intermediate materials in its possession and Control, TBIL shall, at Takeda's request, transfer such quantities to Takeda. Takeda shall pay TBIL $[***] for the transfer of approximately [***] grams (i.e., between [***] and [***] grams) of the Compound, which represents TBIL's remaining inventory of the Compound as of the Effective Date.

7.2 Post-Transfer Responsibility. Except as otherwise expressly provided herein, after the completion of the transfer under Section 7.1, Takeda shall have sole responsibility, at its own expense, to Manufacture the Compound and the Products for Development and Commercialization in the Field in the Territory to develop, or have developed, a process for the Manufacture of the Products, and to scale up (or have scaled-up) such process to a level sufficient to Manufacture (or have Manufactured) and supply reasonable quantities of the Products for Development and Commercialization in accordance with the terms hereof. Takeda shall ensure that the Products are Manufactured in accordance with all Applicable Laws (including GMP).

ARTICLE VIII
PAYMENTS

8.1 Upfront Payment. Within ten (10) Business Days after Takeda's receipt of an invoice from TBIL provided on or after the Effective Date, Takeda shall pay to TBIL a one-time, non-creditable, non-refundable upfront payment of Fifteen Million U.S. Dollars ($15,000,000 USD) (the "Upfront Payment").

8.2 Milestone Payments.

(a) General. Takeda shall pay to TBIL each of the Development, Regulatory Approval and First Commercial Sale Milestone Payments and the Aggregate Sales Milestone Payments (each, a "Milestone Payment") upon achievement of the corresponding milestone event described herein (each such event, a "Milestone Event"). For clarity, no Milestone Payment shall be owed for a Milestone Event that is not achieved, except in the event that (i) upon achievement of an Aggregate Sales Milestone Event for all Products, if any Milestone Payment for the achievement of an earlier Aggregate Sales Milestone Event for all Products was

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not paid by Takeda, such unpaid Milestone Payment shall be paid concurrently with the Milestone Payment that corresponds to the Milestone Event that was achieved.

(b) Development, Regulatory Approval and First Commercial Sale Milestone Payments.

(i) General. Each Milestone Payment (as set forth in the table below) shall be paid one time only upon the first achievement of the Milestone Event by the first Product to achieve such Milestone Event, regardless of how many times the corresponding Milestone Event achieved by the same or different Product(s).

Milestone Event	Milestone Payment
First dosing of a patient in a Phase III Clinical Trial for an IV Formulation	$ [***]
Regulatory Approval of an IV Formulation in a Major Market Country without a CVOT (the "Regulatory Approval Milestone")	$ [***]
First Commercial Sale of an IV Formulation in a Major Market Country	$ [***]
First dosing of a patient in a Phase II Clinical Trial for an Oral Formulation	$ [***]
First dosing of a patient in a Phase III Clinical Trial for an Oral Formulation	$ [***]
First Commercial Sale of an Oral Formulation in a Major Market Country	$ [***]

(c) Aggregate Sales Milestones. Each Aggregate Sales Milestone Payment (each, an "Aggregate Sales Milestone Payment") (as set forth in the table below) shall be paid one time only upon the first instance that the total aggregate Net Sales of all Products during a Calendar Year reach or exceed the amounts set forth in the following tables (each, an "Aggregate Sales Milestone Event"). Takeda shall notify TBIL in writing within thirty (30) days after the end of the Calendar Quarter in which any such Aggregate Sales Milestone Event is achieved, and within thirty (30) days after Takeda's receipt of an invoice from TBIL, Takeda shall pay the applicable Aggregate Sales Milestone Payment to TBIL.

Milestone Event	Milestone Payment
Upon the first occasion that aggregate annual Net Sales for all Products > $[***]	$ [***]

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Milestone Event	Milestone Payment
Upon the first occasion that aggregate annual Net Sales for all Products > $[***]	$ [***]
Upon the first occasion that aggregate annual Net Sales for all Products > $[***]	$ [***]
Upon the first occasion that aggregate annual Net Sales for all Products > $[***]	$ [***]

8.3 Royalties.

(a) General Terms. Within [***] days after the end of each Calendar Quarter, Takeda shall pay TBIL any and all Royalties on Net Sales in such Calendar Quarter as described in this Section 8.3. The Parties hereby acknowledge and agree that (i) the Royalties are blended royalty rates that reflect the combined consideration for the rights granted under the TBIL Know-How, the TBIL Patents, and all Know-How Developed during the Term, which blended rate is applied herein for convenience and amortized over a minimum [***] year period and (ii) access to the TBIL Know-How and Know-How Developed during the Term provides Takeda with a competitive advantage in the marketplace beyond the exclusivity afforded by the TBIL Patents and any Regulatory Exclusivity. Subject to Section 8.3(b) through Section 8.3(d), Section 8.4(a) and Section 8.5 and in accordance with Section 8.3(d), Takeda shall pay to TBIL incremental royalties on aggregate Net Sales by Takeda, its Affiliates and its Sublicensees of all Products in the Territory during a Calendar Year ("Royalties") in the amounts set forth in the table in this Section 8.3, below.

Aggregate Annual Net Sales of all Products in the Territory	Royalty Rate
On the portion of aggregate annual Net Sales of all Products ≤ $[***]	[***]%
On the portion of aggregate annual Net Sales of all Products > $[***] and ≤ $[***]	[***]%
On the portion of aggregate annual Net Sales of Products > $[***]	[***]%

By way of example, if the aggregate annual Net Sales of all Products in the Field throughout the Territory in a Calendar Year equals $[***] USD assuming no deductions pursuant to Section 8.3(c) or Section 8.4, the Royalties would be calculated as follows:

$[***]	x	[***]%	=	$[***]
$[***]	x	[***]%	=	$[***]
$[***]	x	[***]%	=	$[***]
Total				$[***]

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(b) Royalty Term. For purposes of this Agreement, "Royalty Term" shall be determined on a Product-by-Product and county-by-country basis for each Product and shall commence on the First Commercial Sale of such Product in such country and shall continue until the latest of: (i) the expiration of the last Valid Claim from a TBIL Patent or a Takeda Patent Covering the Product that provides market exclusivity for such Product in such country; (ii) any Regulatory Exclusivity for such Product in such country; or (iii) the [***] year period beginning on the First Commercial Sale of such Product in such country. For the avoidance of doubt, "Takeda Patent" as used in this Section 8.3(b) includes Patents claiming or disclosing Joint Know-How to the extent such Patents Cover the Compound or the Product. Following expiration of the Royalty Term in each country, Takeda shall have a non-exclusive, royalty-free, fully paid up, perpetual, irrevocable license under the TBIL Technology with respect to such Product in such country.

(c) Reduction in Royalty Rate Based on Generic Competition. On a Product-by-Product basis and country-by-country basis, following the First Commercial Sale of a Generic Product of a Product in a country in the Territory, in the event that, during any Calendar Quarter, Product Share of such Product in such country (i) is greater than [***] and less than or equal to [***], the royalty rates set forth in Section 8.3(a) shall be reduced by [***]; (ii) is greater than [***] and less than or equal to [***], the royalty rates set forth in Section 8.3(a) shall be reduced by [***]; and (iii) is less than [***], Takeda shall have no obligation to pay TBIL a royalty on Net Sales of such Product in such country, for such Calendar Quarter and for so long as such reduction applies. For the avoidance of doubt, Section 8.3(c)(iii) is not subject to the limitations set forth in Section 8.5.

(d) Royalty Reports.

(i) As soon as reasonably practicable (but in no event more than [***] Business Days) after the end of each Calendar Quarter, Takeda shall submit to TBIL a report setting forth for each Product sold by or on behalf of Takeda, its Affiliates or its Sublicensees the estimated number of units sold, the gross sales and the estimated Net Sales of such Product in such Calendar Quarter.

(ii) Within [***] days after the end of each Calendar Quarter, Takeda shall submit to TBIL a report of Net Sales of Products by or on behalf of Takeda, its Affiliates, and its Sublicensees in sufficient detail to permit confirmation of the accuracy of the payments that are owed or made, including, on a country-by-country and Product-by-Product basis, the number of Products sold, the gross sales, the deductions therefrom, and Net Sales of such Products, the amount and type of Royalties payable, the method used to calculate the Royalties, any reductions to Royalties under Sections 8.3(c)(i), 8.3(c)(ii), 8.3(c)(iii) or Section 8.4(a), any Milestone Payments that are payable and the exchange rates used.

8.4 Third Party Payments.

(a) If Takeda determines that it is desirable to obtain a license or other rights to any Patents of a Third Party required to secure freedom to operate on composition of matter or use of the Compound in the Field in the Territory, Takeda shall be primarily responsible for negotiating and executing the terms of such license or other rights. Prior to entering into such

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license, Takeda shall generally inform TBIL of such license, including Takeda's reasoning for why such license is appropriate and a general description of the fees to be paid by Takeda under such license in connection with freedom to operate on composition of matter or use of the Compound in the Field in the Territory. Takeda shall provide TBIL with a copy of any such agreement no later than [***] days after each such agreement (or any material amendment thereto) has been executed; provided that Takeda shall have the right to redact commercially sensitive information from such copies, further, provided that Takeda shall not redact any information that pertains to the compliance of such agreement with this Section 8.4(a). For clarity, information regarding the scope of the license grants, territory, and royalties, milestones, and upfront payments for which Takeda is seeking an offset right and/or term of each agreement shall not be considered commercially sensitive (and shall not be redacted). As between the Parties, any amounts (whether in the form of upfront payments, royalties, milestones or other amounts) due in connection with such license or other rights will be Takeda's sole responsibility; provided that, to the extent that any such Patent is required to secure freedom to operate on composition of matter or use of the Compound in a country in the Territory hereunder (such Patents, the "Third Party IP"), Takeda may deduct, from the Royalties that are owed to TBIL, [***] of the applicable royalties, upfront payments, and milestone payments and other amounts attributable to the freedom to operate on composition of matter or use of the Compound actually paid to the applicable Third Party for a license or other rights to Third Party IP that is necessary to practice the TBIL Technology in connection with freedom to operate on composition of matter or use of the Compound in the Field in the Territory, provided that the Royalties payable to TBIL in a particular Calendar Quarter are not reduced by more than [***] of the total Royalties that would otherwise be due for such Calendar Quarter in the absence of such reduction. Any portion of such Third Party payments that remains uncredited due to the application of such floor may be carried forward and deducted from Royalties due for subsequent Calendar Quarters until fully exhausted. For clarity, Third Party IP shall not include any Patents on any materials or components unrelated to the Compound, such as carriers, excipients, additives or preservatives used in a formulation of the Product, or devices and equipment used to administer the Product.

(b) Notwithstanding the foregoing Section 8.4(a), in the event and to the extent that a Party had actual knowledge of any Third Party IP prior to the Effective Date, such Party shall be solely responsible for any amounts owed to such Third Party that arise from the Exploitation of the Products in accordance with this Agreement to the extent based upon a license or other rights to such Third Party IP. For the avoidance of doubt, any amounts paid by TBIL pursuant to this Section 8.4(b) shall be paid by directly by TBIL and shall not be considered for the purposes of Section 8.5.

(c) In the event that Takeda decides that obtaining a license from a Third Party in accordance with Section 8.4(a) or Section 8.4(b) is not commercially feasible, the Parties shall confer as to whether it is more reasonable to modify the current activities with respect to the applicable Product so as to render the activity non-infringing or to terminate this Agreement with respect to such Product; provided that the foregoing shall not limit Takeda's rights under Section 15.5.

8.5 Royalty Floor. Notwithstanding the other limitations set forth in Section 8.3(c) and Section 8.4(a), on a Calendar Quarter-by-Calendar Quarter basis, the maximum allowable combined reduction of a royalty payment in a Calendar Quarter pursuant to Section 8.3(c)(i),

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Section 8.3(c)(ii) and Section 8.4 shall be [***]. Takeda may carry forward to a subsequent Calendar Quarter any reduction in a royalty payment which Takeda would have otherwise been allowed to make under Section 8.3(c)(i), Section 8.3(c)(ii) or Section 8.4 in a Calendar Quarter, but for the application of the royalty floor in this Section 8.5. For illustration purposes only, examples of royalty calculations are included in Exhibit 8.5 of this Agreement.

8.6 Reimbursement of TBIL Expenses. Takeda shall reimburse TBIL for those TBIL Internal Costs and its and its Affiliates' Third Party Expenses as provided in Section 4.3, Section 4.7, Section 5.4, Section 7.2, Section 12.3 and Section 15.8 (the "Reimbursed Expenses"). TBIL shall be reimbursed for such amounts in accordance with Section 8.10. Within [***] days of the end of each Calendar Quarter, TBIL shall submit an invoice to Takeda for the Reimbursed Expenses incurred during such Calendar Quarter, together with a written report setting forth in reasonable detail such expenses. Reimbursed Expenses incurred shall include any pre-paid amounts and accrued amounts (to the extent not previously captured as a pre-paid amount). In the event the Reimbursed Expenses in the aggregate exceed the amount set forth in the applicable Development Plan, Commercialization Plan, or the Transfer Plan, as applicable, for any Calendar Quarter by more than [***], the JSC shall determine if such excess amount or any portion thereof, is reasonable under the circumstances. If the JSC determines such excess amount is reasonable, such amount shall be deemed a Reimbursed Expense; otherwise, the excess amount shall be the responsibility of TBIL. If the JSC cannot reach a consensus regarding the reasonableness of the disputed Reimbursed Expenses, such dispute shall be resolved in accordance with Article XVI. For the avoidance of doubt, neither Party shall have final decision-making authority with respect to whether a Reimbursed Expense was reasonable.

8.7 Co-Funding of CVOT. If, subsequent to Takeda's payment of the Regulatory Approval Milestone Payment to TBIL and during the five (5)-year period following First Commercial Sale of an IV Formulation [***], a Regulatory Authority notifies Takeda that a CVOT is required with respect to such IV Formulation [***], TBIL agrees to reimburse Takeda in the amount of [***] of the costs and expenses, including, without limitation, Takeda's Internal Expenses and Third Party Expenses, of such CVOT up to TBIL having reimbursed Takeda [***]. Takeda shall submit an invoice to TBIL for such costs and expenses on a Calendar Quarter basis, and TBIL shall pay such invoices in accordance with Section 8.10. In this event, the Parties will utilize the JSC (reinstating it if necessary) to manage, oversee and coordinate the CVOT under and pursuant to the terms and conditions set forth in Article II hereof; provided, that, such management, oversight and coordination would only continue for such time that TBIL was reimbursing Takeda's costs pursuant to this Section 8.7.

8.8 GAAP/IFRS. All financial terms and standards defined or used in this Agreement for sales or activities shall be governed by and determined in accordance with IFRS, if with respect to Takeda, and GAAP, if with respect to TBIL.

8.9 Currency Conversion. For the purpose of calculating any sums due or otherwise reimbursable by a Party pursuant to this Agreement, any amount expressed in a foreign currency (including any Net Sales expressed in currencies other than Dollars) shall be converted into Dollars by using the average daily exchange rate for such other currency that is used by the applicable Party to prepare its audited financial statements for external reporting purposes for the

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applicable calendar month or Calendar Quarter; provided that such method complies with IFRS and uses a widely accepted source of published exchange rates (e.g., the Wall Street Journal).

8.10 Manner of Payments. Except as otherwise set forth in this Agreement, the Party to whom any amounts are owed hereunder shall provide an invoice to the Party that owes such amounts and such Party that owes such amounts shall pay such amounts within [***] days of receipt of an invoice therefor. All payments to a Party by the other Party hereunder shall be made in Dollars by bank wire transfer in immediately available funds to such bank account(s) that such other Party designates in writing. The Party that owes any amounts hereunder shall notify the other Party as to the date and amount of any such wire transfer at least [***] Business Days prior to such transfer. A Party may dispute an invoice provided it does so within [***] Business Days of receipt thereof and provides the invoicing Party written notice of the reason for the dispute. The invoicing Party must provide supporting documentation for any disputed invoice within [***] Business Days after receiving any such notice. If a correction is warranted, a corrected invoice will be sent and the receiving Party will pay the corrected amount within [***] days after receipt of the corrected invoice. While the Parties work to resolve good-faith disputes under this Section 8.10, neither Party will be deemed to be in breach of the Agreement with respect to the amounts subject to such dispute.

8.11 Late Payments. Any undisputed amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by Applicable Law, at the average one-month London Inter-Bank Offering Rate (LIBOR) for the Dollar as reported from time to time in The Wall Street Journal (or successor publication thereto) plus two percent (2%) annually (compounded quarterly), effective for the first date on which payment was delinquent and calculated on the number of days such payment is overdue or, if such rate is not regularly published, as published in such source as the Parties agree upon in writing. In the event that such rate is not published regularly by The Wall Street Journal (or successor publication thereto), the Parties shall agree on an alternative similar source.

8.12 Taxes.

(a) Any taxes, levies or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by one of the Parties (the "Withholding Party") on account of monies payable to the other Party under this Agreement shall be deducted from the amount of monies otherwise payable to the other Party under this Agreement. Upon payment of applicable Taxes, the Withholding Party shall promptly provide to the other Party original or certified copies of all tax payments or other sufficient evidence of tax payments made the Withholding Party pursuant to the Agreement or certificate of the other Parties exemption from obligation to pay such taxes. The Parties shall use reasonable efforts to legally reduce Taxes imposed on payments made pursuant to this Agreement.

(b) Tax Certifications. A Party receiving a payment pursuant to this Article VIII shall timely provide the remitting Party appropriate certification from the relevant revenue authorities (i) of such Party's jurisdiction of tax residence and (ii) of such Party's entitlement to the benefit of any applicable income tax treaty if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

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(c) If a Party that owes a payment under this Agreement assigns its rights and obligations to any Person and if, as a result of such assignment, the withholding or deduction of tax required by Applicable Laws with respect to payments under this Agreement is increased, then, subject to Section 8.12(d), any amount payable under this Agreement shall be increased to take into account such withheld or deducted taxes as may be necessary so that, after making all required withholdings and deductions (including withholdings and deductions on amounts payable under this Section 8.12(c), the payee receives an amount equal to the sum it would have received had no such increased withholding or deduction been made. For the avoidance of doubt, if a payee under this Agreement assigns its rights and obligations under this Agreement, the payee shall not be entitled to any additional payments with respect to Taxes arising as a result of such payee's assignment.

(d) To the extent a payee obtains any credit for Taxes for which it has received a payment pursuant to Section 8.12(c) against any liability for tax in the year in which the receipt is taxable, any preceding years, or any succeeding years within the term of this Agreement, thereby reducing out-of-pocket tax payments by the payee in such year or years, calculated on a "with and without" basis, the payee shall promptly reimburse the payor an amount equal to its tax savings resulting from such credit and the payee shall timely provide the payor with reasonable evidence as may reasonably be requested to determine whether any amounts are subject to reimbursement pursuant to this Section 8.12(d).

8.13 Books and Records. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with IFRS for Takeda and GAAP for TBIL) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement for at least the three (3) preceding twelve (12)-month periods to which the applicable entries relate or such longer period as required by Applicable Law.

8.14 Audits and Adjustments.

(a) Each Party (the "Auditing Party") shall have the right, upon reasonable written notice to the other Party (the "Audited Party") and during normal business hours to have the books and records of the Audited Party, its Affiliates, and in the case of TBIL, the Audited Party's Sublicensees for the preceding three (3)-year period, to the extent necessary to verify the Royalties, Aggregate Sales Milestone Payments or Reimbursed Expenses that are payable under this Agreement, audited by an independent certified public accountant appointed by the Auditing Party and reasonably acceptable to the Audited Party (which accountant shall be subject to reasonable confidentiality and non-use restrictions) for the sole purpose of verifying the accuracy of all accounting reports and payments made in connection with this Agreement. Neither Party, nor any of its Affiliates or in the case of Takeda, its Sublicensees, may be subject to such an audit more than one time in a twelve (12)-month period, unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found. Such accountants shall be instructed not to, and shall not, reveal to the Auditing Party the details of its review, except for such information as is required to notify the Auditing Party of any inaccuracy of any report or payment, which shall be presented in a summary fashion and be subject to the confidentiality provisions contained in Article IX.

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(b) All expenses incurred in connection with performing any such audit shall be paid by the Auditing Party unless the audit discloses at least a five percent (5%) shortfall in the Royalties or Aggregate Sales Milestone Payments paid or overcharge of the Reimbursed Expenses invoiced for the audited period, in which case the Audited Party shall reimburse the Auditing Party its Third Party Expenses incurred in connection therewith. The Auditing Party shall be entitled to recover any shortfall in payments due to it or overcharge in payments made by it as determined by such audit, plus interest thereon calculated in accordance with Section 8.11. For clarity, the documents from which were calculated any sums due under this Section 8.14 shall be retained by the relevant Party in accordance with the terms hereof.

(c) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Section 16.1(a).

8.15 [***] Payments to Takeda. Within [***] days of [***], if any, TBIL shall pay Takeda [***]:

(a) [***], and during such Calendar Quarter, Takeda, its Affiliates or its or their Sublicensees are Commercializing an IV Formulation in such Indication; and

(b) [***] and during such Calendar Quarter, Takeda, its Affiliates or its or their Sublicensees is Commercializing an IV Formulation in such country.

ARTICLE IX
CONFIDENTIALITY

9.1 Confidential Information. "Confidential Information" means all secret, confidential or proprietary information, data and know-how whether provided in written, oral, graphic, video, computer or other form, provided by or on behalf of one Party or its Affiliates or, in the case of Takeda, its Sublicensees or Subcontractors (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") pursuant to this Agreement, including information relating to the Disclosing Party's existing or proposed research, development efforts, unpublished Patent applications, businesses or products, processes, new product developments, product designs, formulae, technical information, laboratory data, clinical data, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of the Disclosing Party and any other materials that have not been made available by the Disclosing Party to the general public. Notwithstanding the foregoing, Confidential Information shall not include any information that the Receiving Party can establish with competent written proof:

(a) was already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

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(c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

(d) was lawfully disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by or on behalf of the Receiving Party without the use of or reference to the Confidential Information of the Disclosing Party;

provided that, in each of the foregoing Section 9.1(a) through Section 9.1(e), such information shall not be deemed to be within the foregoing exceptions merely because such information is embraced by more general knowledge that is publicly known or in the Receiving Party's possession, and no combination of features shall be deemed to be within the foregoing exceptions merely because individual features are publicly known or in the Receiving Party's possession, unless the particular combination itself and its principle of operations are in the public domain or in the Receiving Party's possession without the use of or access to the Disclosing Party's Confidential Information.

9.2 Confidentiality and Non-Use Obligations. Except as expressly provided in this Article IX, or otherwise agreed in writing by the Parties, the Parties agree that (a) each Party shall not disclose to any Third Party, and shall keep in confidence, all Confidential Information of the other Party, using the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases with no less than a reasonable degree of care and (b) each Party may use the other Party's Confidential Information only to perform its obligations or exercise its rights under this Agreement.

9.3 Permitted Disclosures. Notwithstanding Section 9.2, the Receiving Party may disclose the Disclosing Party's Confidential Information to the extent reasonably necessary in the following circumstances:

(a) subject to Section 9.7, if the Receiving Party reasonably determines that it must disclose Confidential Information of the other Party (i) based on the advice of counsel, to comply with Applicable Laws, including as promulgated by any securities exchanges or under the HSR Act, or (ii) to comply with a valid order, demand or request of a court of competent jurisdiction or other Governmental Authority; provided that, with respect to the foregoing subsections (i) and (ii), the Receiving Party provides the Disclosing Party, to the extent practicable, with reasonable advance written notice thereof and reasonably cooperates with the Disclosing Party to obtain confidential treatment and, if available, an appropriate protective order therefor, and only furnishes that Confidential Information that it is advised by counsel that it is legally required to furnish;

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(b) to patent offices in order to seek or obtain Patents to the extent permitted hereunder or Regulatory Authorities in connection with any Regulatory Materials submitted thereto in accordance with this Agreement;

(c) to its Affiliates and directors, managers, officers, employees, agents, contractors and advisors of it and its Affiliates to the extent reasonably necessary for the Receiving Party to perform its obligations or exercise its rights under this Agreement; provided that each such recipient of Confidential Information has a need to know such information and must be bound by obligations of confidentiality and non-use (which shall be in writing or by operation of law for all Third Parties) no less restrictive than those set forth in this Article IX prior to any such disclosure;

(d) to any existing or potential Subcontractors, licensees or Sublicensees with respect to any Product, Takeda Technology or TBIL Technology in connection with such Receiving Party's exercise of its rights or performance of its obligations under this Agreement; provided that each such recipient of Confidential Information has a need to know such information in furtherance of such exercise of rights and/or performance of obligations under this Agreement, and must be bound by obligations of confidentiality and non-use (which shall be in writing for all Third Parties) no less restrictive than those set forth in this Article IX (but which may be of shorter duration for Third Parties, but at least five (5) years, if and only if the Receiving Party uses reasonable efforts to obtain a term of such obligations equal to that herein) prior to any disclosure;

(e) to existing or potential investors, lenders, other sources of funding, acquirors and sellers, and their respective accountants, financial advisors and other professional representatives; provided that such disclosure shall be made only to the extent customary in the applicable circumstances and such Persons have a need to know such information for purposes of the applicable investment, loan, purchase or sale and must be bound by customary obligations of confidentiality and non-use (which shall be in writing for all Third Parties) no less restrictive than those set forth in this Article IX (but which may be of shorter duration for Third Parties, but at least five (5) years, if and only if the Receiving Party uses reasonable efforts to obtain a term of such obligations equal to that herein) prior to any such disclosure; and

(f) upon the prior written consent of the Disclosing Party.

Notwithstanding the foregoing, in the event the Receiving Party makes a disclosure of the Disclosing Party's Confidential Information to any Person pursuant to any of Sections 9.3(a) through 9.3(f), the Receiving Party shall be liable for any failure by any such Person to comply with the confidentiality and non-use provisions set forth in this Article IX. Notwithstanding anything to the contrary herein, nothing in this Agreement shall be construed to require either Party to disclose to the other Party any information that is subject to the terms of a non-disclosure agreement or undertaking with a Third Party or information that constitutes privileged attorney-client communications or attorney work-product.

9.4 Publications. In the event that a Party (the "Publishing Party") wishes to publish the results or other information related to any Compound or Product in any scientific journals or publication or as part of any scientific presentation, the Publishing Party shall provide the other

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Party with an advance copy of such proposed publication or summary of such proposed presentation (as applicable) prior to submission for publication or presentation, and such other Party shall then have (a) thirty (30) days prior to submission of such publication, or (b) fifteen (15) days prior to submission of the abstract or presentation, to recommend any changes it reasonably believes are necessary to preserve any Patent rights or Confidential Information belonging in whole or in part to such other Party or any of its Affiliates. If such other Party informs the Publishing Party that such publication or presentation in such other Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to such other Party or any of its Affiliates (other than pursuant to a license granted under this Agreement), or any Confidential Information of such other Party, the Publishing Party shall delay or prevent such publication or presentation as follows: (x) with respect to a patentable invention, such publication or presentation shall be delayed sufficiently long (not to exceed sixty (60) days) to permit the timely preparation and filing of a Patent application; and (y) with respect to any such Confidential Information, such Confidential Information shall be deleted from the publication or presentation.

9.5 Public Announcements. Following the execution of this Agreement, the Parties shall jointly issue a press release in the form attached as Schedule 9.5. Following issuance of such press release, each Party may issue additional press releases and make other public statements or disclosures regarding the subject matter of this Agreement; provided that such Party obtains the other Party's prior written consent, except such consent shall not be required to the extent such disclosure (a) is required by Applicable Law (in which case, the Parties shall comply with the applicable provisions of this Agreement), (b) is permitted pursuant to Section 9.4, or (c) has been previously approved for disclosure in accordance with this Section 9.5 or otherwise made public not in breach of the terms of this Article IX.

9.6 Use of Names. Except as otherwise expressly set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; provided that, subject to Sections 9.3 and 9.7, either Party may use the name of the other Party in any document filed with any Regulatory Authority or Governmental Authority, including the FDA, EMA and the SEC.

9.7 Securities Filings. Notwithstanding anything to the contrary herein, if a Party is required by Applicable Law to disclose a copy of this Agreement and its terms to the SEC or any other Governmental Authority, such Party shall permit the other Party to review and comment upon the draft thereof (including a proposed redacted version and a confidential information request). Such draft filing will be provided to the other Party reasonably in advance of the deadline for such securities filing, and such other Party shall promptly (and in any event, no less than [***] Business Days (or such shorter time to meet any filing deadline where it was not practical to provide the other Party with such notice)) review and provide comments thereon. The Party seeking such disclosure will exercise reasonable efforts to obtain confidential treatment of this Agreement from the applicable Governmental Authority as represented by the redacted version reviewed by the other Party.

9.8 Survival. The obligations and prohibitions contained in this Article IX shall survive the expiration or termination of this Agreement for a period of [***] years; provided that,

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with respect to any Confidential Information that qualifies as a trade secret under Applicable Law, such obligations and prohibitions shall survive for so long as such Confidential Information qualifies as a trade secret under Applicable Law.

ARTICLE X
REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party, as of the Execution Date and the Effective Date, that:

(a) Existence; Good Standing. It is (i) duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated and (ii) duly licensed or qualified to do business and is in good standing under the Applicable Laws of each jurisdiction where its ownership or lease of property or the nature or conduct of its business requires such qualification, except with respect to its commercial operations where the lack of such qualification as of the Execution Date or Effective Date does not have a material adverse effect on its financial condition or its ability to perform its obligations hereunder.

(b) Authority; Binding Effect. It has all requisite corporate power and authority to execute this Agreement and to perform its obligations hereunder. It has duly executed and delivered this Agreement to the other Party and, assuming this Agreement has been duly executed and delivered by the other Party, this Agreement constitutes a valid and binding obligation of it, in each case enforceable against it in accordance with its terms, except as enforcement may be limited by bankruptcy or similar laws affecting creditors' rights generally or by general principles of equity (regardless of whether enforcement is sought in a proceeding in equity or at law).

(c) No Conflicts. The execution and delivery of this Agreement by it and the performance by it contemplated hereunder do not and will not (i) contravene or conflict with its certificate of incorporation or bylaws, (ii) contravene or conflict with or constitute a material default under any of its contracts or judgments related to the Products binding upon or applicable to it or any of its Affiliates, or (iii) assuming the making of the filings described in Section 10.1(d) and the receipt of all consents, approvals, authorizations, or waiting period expirations or terminations as described in Section 10.1(d), contravene or conflict with or constitute a default under any provision of any Applicable Law binding upon or applicable to it or any of its Affiliates. For clarity, and notwithstanding the foregoing, no representation or warranty shall be deemed to be made in the foregoing subsection (iii) in connection with any subject matter related to Intellectual Property.

(d) Consents. Except with respect to any filings pursuant to the HSR Act and any comparable Applicable Law in jurisdictions outside the U.S. related to the approval of transactions similar to those contemplated under this Agreement, as of the Execution Date, all necessary consents, approvals, authorizations, waiting period expirations or terminations of, and all notices to, and filings by it with, all Governmental Authorities and other Persons required to be obtained or provided by it as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided.

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10.2 TBIL Representations and Warranties. Except as set forth in Schedule 10.2, TBIL hereby represents and warrants to Takeda, as of the Execution Date and the Effective Date, that:

(a) Infringement of Third Party IP. No action, suit, claim, arbitration, or proceeding is pending, or threatened in a writing received by TBIL or any of its Affiliates, that the Development or Commercialization (including any related Manufacturing) of any Product infringes, misappropriates, or otherwise violates any Person's Intellectual Property rights, and there has been no such claim asserted or threatened in a writing received by TBIL or any of its Affiliates against it or any of its Affiliates. To TBIL's Knowledge, the Development and Commercialization of the Products will not infringe, misappropriate, or otherwise violate any Person's Intellectual Property rights.

(b) Infringement of TBIL Technology. No Person is, to its Knowledge, infringing, misappropriating, or otherwise violating any of the TBIL Technology, and no such claims have been asserted or threatened in writing against any Person by it or any of its Affiliates.

(c) Validity; Enforceability. There has been no claim asserted or threatened in a writing received by TBIL or any of its Affiliates challenging the scope, validity, or enforceability of any Patents or Patent applications included in the TBIL Patents owned by it or any of its Affiliates.

(d) Government Funding. No funding, facilities or personnel of any Governmental Authority were used, directly or indirectly, to develop or create, in whole or in part, any of the TBIL Technology.

(e) Disclosure Related to the Compound. It (i) has made available or disclosed to Takeda all INDs and all other material filings and correspondence with any Regulatory Authorities filed by or on behalf of TBIL and/or any of its Affiliates relating to the Compound, and (ii) has not failed to disclose or make available to Takeda any material information within the Knowledge of it or any of its Affiliates related to the Compound or any Product.

(f) Development Activities. All Development activities related to the Compound have been conducted by or on behalf of TBIL and/or its Affiliates in compliance with all Applicable Laws.

(g) Privacy. To its Knowledge as of the date hereof, and except as would not have a material adverse effect, it and its Affiliates are in compliance with Applicable Laws, as well as its and its Affiliates' own policies, relating to privacy, data protection, and the collection and use of personal information collected, used, or held for use by it and its Affiliates, and no claims are pending or threatened in a writing received by TBIL or any of its Affiliates against it or any of its Affiliates alleging a violation of any Person's privacy or personal information.

(h) Third Party Agreements. TBIL has provided Takeda with a true and correct copy of all agreements pursuant to which a Third Party grants TBIL or any of its

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Affiliates, or TBIL or any of its Affiliates grants to a Third Party, a license or other rights to the TBIL Technology or the Development, Commercialization or other Exploitation of any Product for use in the Field in the Territory (including, for clarity, any and all amendments thereto) prior to or as of the Effective Date and except as provided for in such agreements, it and to its Knowledge, the counterparties, are in compliance in all material respects with the terms of such agreements.

(i) TBIL Patents. TBIL hereby represents and warrants to Takeda that Exhibit 1.1(b) sets forth a correct and complete list (in all material respects) of all TBIL Patents owned by TBIL or any of its Affiliates, and TBIL represents and warrants that all such Patents are in effect and subsisting.

(j) Inter-Company Agreements. TBIL has provided Takeda with a true and correct copy of all agreements pursuant to which an Affiliate of TBIL grants TBIL or its Affiliate, or TBIL grants to its Affiliate, a license or other rights to the TBIL Technology or the Development, Commercialization or other Exploitation of any Compound or Product for use in the Field in the Territory (including, for clarity, any and all amendments thereto) prior to or as of the Execution Date, and except as provided for in such agreements, TBIL and its Affiliates are in compliance in all material respects with the terms of such agreements. For the sake of clarity, any and all such agreements are Confidential Information of TBIL and its Affiliates.

10.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN SECTION 10.1 OR SECTION 10.2, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING: (a) CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT IN THE FIELD; (b) THAT ANY PRODUCT MADE, USED, SOLD OR OTHERWISE DISPOSED OF UNDER THIS AGREEMENT IS OR WILL BE FREE FROM INFRINGEMENT OF PATENTS, COPYRIGHTS, TRADEMARKS, INDUSTRIAL DESIGN OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY; (c) REGARDING THE EFFECTIVENESS, VALUE, SAFETY, NON-TOXICITY, PATENTABILITY, OR NON-INFRINGEMENT OF ANY PATENTED TECHNOLOGY, THE PRODUCTS OR ANY INFORMATION OR RESULTS PROVIDED BY EITHER PARTY PURSUANT TO THIS AGREEMENT; (d) THAT ANY PRODUCT WILL OBTAIN THE NECESSARY REGULATORY APPROVALS, AND/OR; (e) WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EACH PARTY EXPLICITLY ACCEPTS ALL OF THE SAME AS EXPERIMENTAL AND FOR DEVELOPMENT PURPOSES, AND WITHOUT ANY EXPRESS OR IMPLIED WARRANTY FROM THE OTHER PARTY.

10.4 Inventory and Other Transferred Materials. SUBJECT TO THE EXPRESS TERMS OF THIS AGREEMENT, TAKEDA ACKNOWLEDGES AND AGREES THAT ANY AND ALL INVENTORY AND OTHER DOCUMENTS AND MATERIALS PROVIDED TO TAKEDA BY OR ON BEHALF OF TBIL OR ANY OF ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT ARE EXPERIMENTAL IN NATURE AND MAY HAVE UNKNOWN CHARACTERISTICS. TAKEDA SHALL USE PRUDENCE AND

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REASONABLE CARE IN THE USE, HANDLING, STORAGE, TRANSPORTATION, DISPOSITION, AND CONTAINMENT OF SUCH TRANSFERRED ITEMS. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, WITHOUT LIMITING THE FOREGOING, ANY AND ALL TRANSFERRED ITEMS ARE MADE AVAILABLE ON AN "AS IS" BASIS, WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

10.5 Covenants. Each Party hereby covenants and agrees as of the Execution Date and Effective Date, and during the Term:

(a) Each Party hereby covenants and agrees as of the Execution Date and Effective Date, and during the Term:

(i) Debarment. In connection with performing its obligations hereunder, it and its Affiliates shall not use any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or, to its Knowledge, is the subject of debarment proceedings by any Regulatory Authority.

(ii) Compliance with Applicable Laws. It, and its respective Affiliates, shall conduct all activities under and in connection with this Agreement in accordance with Applicable Laws (including GCP, GLP and GMP). Notwithstanding anything to the contrary herein, neither it, nor any of its Affiliates, shall, nor shall be required to, Develop or Commercialize a Product or undertake any other activity under or in connection with this Agreement which violates, or which it reasonably believes, in good faith, will violate, any Applicable Law.

(iii) Negative Covenants. Each Party hereby covenants and agrees that it shall not, and shall ensure that its Affiliates shall not, use or practice any of the other Party's Patents or Know-How to which it is licensed or otherwise granted rights hereunder, except to the extent expressly permitted hereunder.

(b) Governmental Approval.

(i) Each Party hereto shall, or shall cause its ultimate parent entity as that term is defined in the HSR Act to, as promptly as possible, use its reasonable best efforts to (1) take, or cause to be taken, all actions necessary, proper or advisable under Applicable Law or otherwise to consummate and make effective the transactions contemplated by this Agreement, (2) obtain, or cause to be obtained, all consents, licenses, permits, waivers, authorizations, orders and approvals from all Regulatory Authorities or other Governmental Authorities that may be or become necessary for its authorization, execution and delivery of this Agreement, the consummation of the transactions contemplated hereby, and the performance of its obligations pursuant to this Agreement, and (3) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated hereby required to be made by such Party under Applicable Law; provided that, for the avoidance of doubt, the obtaining of any such consent, license, permit,

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waiver, authorization, order or approval shall not be a condition precedent to the obligation of any Party to consummate the transactions contemplated herein (except to the extent provided in Section 10.5(b)(ii)).

(ii) Promptly upon execution and delivery of this Agreement but in no event later than fifteen (15) Business Days thereafter, each of TBIL and Takeda will, or will cause their ultimate parent entities as that term is defined in the HSR Act to, prepare and file, or cause to be prepared and filed, with the appropriate Governmental Authorities, notifications with respect to the transactions contemplated by this Agreement pursuant to the HSR Act and seek early termination of any applicable waiting periods under the HSR Act. Concurrently or thereafter but in any case within fifteen (15) Business days of the Effective Date, each of TBIL and Takeda, as applicable, shall promptly submit all competition filings with respect to the transactions contemplated by this Agreement required by Governmental Authorities outside the U.S. ("Non-U.S. Competition Filings", together with any notification under the HSR Act, "Competition Filings"), supply all information requested by a Governmental Authority in connection with its review of a Competition Filing, and cooperate with each other in responding to any such request. Takeda shall be solely responsible for all filing fees payable to a Governmental Authority required to be paid in connection therewith and Takeda shall take the lead and be responsible for making all required and advisable notifications or filings under any applicable Non-U.S. Competition Filings in jurisdictions in which one notification or filing is required rather than separate filings or notifications by each party.

(iii) Each Party will use its respective reasonable best efforts and will cooperate with the other Party to comply as promptly as practicable with all governmental requirements applicable to the Collaboration and to obtain promptly all approvals, orders, permits or other consents of any applicable Governmental Authorities necessary for the consummation of the contemplated transactions, including by: (1) timely furnishing the other Party all information concerning the Party and its Affiliates that the other Party's counsel reasonably determines is required to be provided by such other Party in order to comply with a governmental requirement applicable to the Collaboration or to obtain one (1) or more such approvals, orders, permits or other consents; (2) promptly providing the other Party with copies of all written communications to or from any Governmental Authority relating to any competition filings submitted in connection with the transactions or any investigation of the transactions by a Governmental Authority; (3) keeping each other reasonably informed of any communication received or given in connection with any proceeding or action regarding the transactions; and (4) permitting TBIL or Takeda (as the case may be) to review and incorporate the other Party's reasonable comments in any communication given by it to any Governmental Authority or in connection with any proceeding related to the HSR Act or other competition filing. Each of the Parties will furnish to the other Party and, upon request by a Governmental Authority, to any Governmental Authority such information and assistance as may be reasonably requested in connection with the foregoing, including by responding promptly to and complying fully with any request for additional information or documents under the HSR Act and other applicable competition laws. Notwithstanding the foregoing, either Party may redact any correspondence, communication, or other materials as necessary to (A) protect unrelated confidential or proprietary information; (B) comply with contractual arrangements, (C) comply with Applicable Law, and (D) address reasonable attorney-client or other privilege or confidentiality concerns. The Parties may, as they deem advisable and necessary, designate

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any competitively sensitive materials provided to the other under this Section 10.5(b) as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel of the recipient and will not be disclosed by such outside counsel to employees, officers, or directors of the recipient without the advance written consent of the party providing such materials. No Party shall participate in any meeting with any Governmental Authority in respect of any such filings, investigation or other inquiry without making reasonable best efforts to consult with the other Party in advance and, to the extent permitted by such Governmental Authority, to give the other Party the opportunity to attend and participate at such meeting.

(iv) Without limiting the generality of Takeda's undertaking pursuant to this Section 10.5(b), Takeda agrees to use its reasonable best efforts to avoid or eliminate any impediment under any antitrust, competition or trade regulation law that may be asserted by any Governmental Authority or any other Party so as to enable the Parties to close the transactions contemplated by this Agreement as expeditiously as possible (the "Closing"); provided, however that notwithstanding anything to the contrary contained in Section 10.5(b) or elsewhere in this Agreement, neither Takeda nor its Affiliates shall have any obligation to, and none of TBIL nor its Affiliates shall (without the prior written consent of Takeda) propose or commit to any Third Party that it, Takeda, or their respective Affiliates will, (1) dispose of or transfer or cause any of them to dispose of or transfer any assets (whether owned or in-licensed), or to commit to cause any of them to dispose of or transfer any assets (whether owned or in-licensed); (2) discontinue or cause any of them to discontinue offering any product or service (in each case, whether owned or in-licensed), or commit to cause any of them to discontinue offering any product or service (in each case, whether owned or in-licensed); (3) license or otherwise make available, or cause any of them to license or otherwise make available, to any Person, any technology or other proprietary rights (in each case, whether owned or in-licensed), or commit to cause any of them to license or otherwise make available to any Person any technology or other proprietary rights (in each case, whether owned or in-licensed), hold separate or cause any of them to hold separate any assets or operations (in each case, whether owned or in-licensed) (either before or after the Closing), or commit to cause any of them to hold separate any assets or operations (in each case, whether owned or in-licensed); (4) make or cause any of them to make any commitment (to any Governmental Authority or otherwise) regarding their future operations or (5) contest any final action or decision taken or made by any Governmental Authority challenging the consummation of the transactions contemplated by this Agreement.

(v) In the event Takeda elects to defend through litigation on the merits any claim asserted in court based on any antitrust, competition or trade regulation law by any Party in order to avoid entry of, or to have vacated or terminated, any governmental order (whether temporary, preliminary or permanent) that would prevent the consummation of the Closing. Takeda shall be entitled to direct the defense of such litigation and any related negotiations, and TBIL and its Affiliates shall not make any offer, acceptance or counter offer to or otherwise engage in negotiations or discussions with any Person with respect to any proposed settlement, consent decree, commitment or remedy, or, in the event of litigation, discovery, admissibility of evidence, timing or scheduling, except as specifically requested by or agreed with Takeda. TBIL shall use its reasonable best efforts to provide full and effective support of Takeda in all material respects in all such negotiations and discussions to the extent

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requested by Takeda, provided that Takeda shall reimburse TBIL for TBIL's or its Affiliates' out-of-pocket payments to a Third Party reasonably incurred in furtherance of such support.

(vi) Prior to the Closing, Takeda shall not and shall cause its Affiliates not to acquire or agree to acquire by merging or consolidating with, or by purchasing a substantial portion of the assets of or equity in, or by any other manner, any Person or portion thereof, or otherwise acquire or agree to acquire any assets, if the entering into of a definitive agreement relating to or the consummation of such acquisition, merger or consolidation would reasonably be expected to impose any significant delay in the obtaining of, or significantly increase the risk of not obtaining, any authorizations, consents, orders, declarations or approvals of any Governmental Authority necessary to consummate the transactions contemplated hereby or the expiration or termination of any applicable waiting period.

(vii) TBIL and Takeda shall use reasonable best efforts to give all notices to, and obtain all consents from, all Third Parties that are described in Schedule 10.5(b)(vii); provided that under no circumstances shall either Party or its Affiliates be required to make any payment to any Person or incur any other liability to secure any Person's consent, and provided further that, for the avoidance of doubt, the obtaining of any such consent, authorization or approval shall not be a condition precedent to the obligation of any Party to consummate the transactions contemplated hereby (except to the extent provided in Section 10.5(b)(ii)).

(c) Anti-Corruption Compliance. Each Party and its Affiliates have been, are, and will remain in full compliance with all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, (15 U.S.C. § 78dd-1, et seq.), the U.K. Bribery Act 2010, and Applicable Laws of other jurisdictions relating to bribery or corruption, and neither such Party nor any of its Affiliates, nor any director, officer, agent or employee of such Party or any of its Affiliates has, directly or indirectly, given, made, offered or received or agreed to give, make, offer or receive or will give, make offer or receive any payment, gift, contribution, expenditure or other advantage: which would violate any Applicable Law; or to or for a Public Official with the intention of: improperly influencing any act or decision of such Public Official; inducing such Public Official to do or omit to do any act in violation of his lawful duty; or securing any improper advantage, in each case in order to obtain or retain business or any business advantage.

(d) Health Care Compliance Matters.

(i) Each Party and its Affiliates are in compliance and have been, are, and will remain in full compliance with all Health Care Laws applicable to such Party or any of its Affiliates. Neither Party nor any of its Affiliates is a party to or has any ongoing reporting obligations pursuant to or under any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Governmental Authority. Additionally, none of such Party, its Affiliates, or any of its respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. state or federal health care program or has been convicted of any crime or, is subject to a Government Proceeding or has engaged in any conduct that could reasonably be expected to result in

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debarment, suspension, or exclusion. Each Party shall promptly provide the other Party with written notification thereof if any of the statements in the second and/or third sentence of this paragraph becomes untrue during the Term.

(ii) Each Party and its Affiliates have been, are and will remain operating in full compliance with all Applicable Laws administered or enforced by the FDA and comparable Governmental Authorities, and with all permits of the FDA and comparable Governmental Authorities which are required for the conduct of their business (collectively, the "FDA Permits"), and such FDA Permits are valid, subsisting, and in full force and effect. Such Party and its Affiliates have not received notice of any pending or threatened Government Proceeding from the FDA, any Governmental Authority, any qui-tam relator or applicable foreign Governmental Authority alleging that any operation or activity of such Party or its Affiliates is in violation of any Applicable Law. Each Party shall promptly provide the other Party with written notification thereof if any of the statements in the second sentence of this paragraph becomes untrue during the Term.

(iii) Neither Party nor any of its Affiliates has been or is the subject of any pending or threatened investigation in respect of such Party, its Affiliates, or its or their products, by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto. Each Party shall promptly provide the other Party with written notification thereof if the statement in the prior sentence becomes untrue during the Term.

(iv) Each Party shall be responsible for tracking and reporting transfers of value paid by, or on behalf of, it or its Affiliates (including any transfers of value by any employees, contractors or agents of a Party or its Affiliates) in accordance with Applicable Law, including the requirements of Section 6002 of the Patient Protection and Affordable Care Act and any other transparency tracking and reporting requirements of any Governmental Authority. For the avoidance of doubt, the Party that makes the transfer of value, or the Party on whose behalf the transfer of value was made, to any Person, including any Third Party, for the activity that triggers a transparency tracking or reporting obligation under the previous sentence, shall be the Party that reports such transfer of value to the relevant Governmental Authority, irrespective of any prepayment, reimbursement or other reconciliation of any expenses between the Parties under this Agreement.

(v) Third Party and Inter-Company Agreements. With respect to any agreements described in Sections 10.2(h) and 10.2(j) (collectively, the "TBIL Agreements"), TBIL covenants that during the Term, (i) it shall (and shall cause its Affiliates to) use all reasonable efforts to satisfy all of its obligations under (including making all payments), and take all reasonable steps necessary to maintain in full force and effect, each of the TBIL Agreements, (ii) it shall not (and shall cause its Affiliates not to) assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 17.8), amend, restate or terminate in whole or in part, or otherwise modify, any of the TBIL Agreements without the prior written consent of Takeda (such consent not to be unreasonably withheld or delayed); provided that with respect to any amendment, restatement or modification, solely to the extent that any such amendment, restatement or modification could reasonably be expected to adversely affect Takeda's rights or obligations under this Agreement

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or the applicable TBIL Agreement, (iii) it shall (and shall cause its Affiliates to) provide Takeda with prompt notice of any claim of a breach under any of the TBIL Agreements or notice of termination of any of the TBIL Agreements, made by any of TBIL, its Affiliates or the applicable Third Party, and (iv) it shall (and shall cause its Affiliates to) promptly send to Takeda copies of all other correspondence regarding the TBIL Agreements, to the extent relevant to the rights or obligations of Takeda under this Agreement.

10.6 Non-Compete.

(a) Non-Compete. From the Effective Date until: (i) the effective date of the expiration of this Agreement; or if applicable, (ii) [***] years after the effective date of the [***] of this Agreement, neither Party nor any of its Affiliates, alone or through or with a Third Party, shall, directly or indirectly, Develop, Manufacture, or Commercialize any Competing Product in any country in the Territory, or grant any Person any right to do so; provided that [***]. In the event that Takeda terminates pursuant to Section 15.5 (Termination for Convenience), the restriction set forth in this Section 10.6(a) shall only apply with respect to [***] (i) [***] and (ii) [***]. The activities described in this Section 10.6(a), if conducted within the applicable time frame, shall be deemed collectively as the "Restricted Activities". Notwithstanding the foregoing, with respect to Takeda, [***], shall not be deemed a [***]. In addition to the restrictions set forth above in this Section 10.6(a), during the Term on a country-by-country basis, TBIL shall not develop or commercialize an intravenously administered formulation of Velusetrag in the U.S., Canada or Japan, or in such other countries in which decisions related to the development and commercialization of Velusetrag are exclusively in TBIL's control. Other than rights granted in the AW Development and Commercialization Agreement, TBIL shall not out-license Velusetrag in a manner that allows development of an intravenously administered formulation of Velusetrag.

(b) Acquisition of Competing Product. Notwithstanding Section 10.6(a), in the event that (i) a Party or any of its Affiliates acquires, or is acquired by, a Person, (ii) a Party or any of its Affiliates acquires all or substantially all of the business or assets of a Person, or (iii) a Person acquires all or substantially all of the business or assets of a Party (in each case whether by merger, stock purchase, change of control or purchase of assets) (each of the foregoing subsections (i), (ii) and (iii), a "Competing Product Transaction"), and with respect to the foregoing (i), (ii) and (iii), such Person or any of its Affiliates is, prior to or as of the date of such transaction, engaged in any activities that would violate Section 10.6(a) if conducted by a Party (such activities, a "Competing Program"), such Party shall promptly provide (or cause to be provided) written notice to the other Party of such Competing Product Transaction within [***] Business Days of the closing of such transaction, which notice shall specify whether such Party and its Affiliates (including, for clarity, any Persons that become Affiliates in connection with or following the Competing Product Transaction) will (1) divest the Competing Program, or (2) terminate the Competing Program. Notwithstanding the foregoing, solely in the event that TBIL is acquired by a Person with a Competing Program, such Competing Program can, subject to the obligations set forth in Section 10.6(b)(iii), be maintained. For the avoidance of doubt, and notwithstanding anything to the contrary herein, neither Party nor its Affiliates may acquire a Competing Program on a standalone basis.

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(i) Divestiture of the Competing Program. In the event that a Party elects to divest the Competing Program as described in Section 10.6(b)(i), such divestiture may occur by either (1) an outright sale of the Competing Program to a Third Party, or (2) an exclusive (including as to such Party and its Affiliates) out-license to a Third Party of the rights to conduct the Restricted Activities; provided that, with respect to the foregoing subsection (2), such Party and its Affiliates may retain residual financial rights to such Competing Program and reversion rights in the case of termination of the out-license agreement (provided that upon such a reversion, the applicable Party would again be subject to the divestiture/termination requirements of this Section 10.6(b), as applicable). In the event that the Party elects to divest the Competing Program, such Party shall, and shall cause its Affiliates to, use Commercially Reasonable Efforts to divest such Competing Program promptly following the closing of the Competing Product Transaction, and in any event, such divestiture shall be completed within [***] year of such closing; provided that such time period shall be extended, if, upon the expiration thereof (and any extensions thereto), such Party provides competent evidence of reasonable ongoing efforts to divest the Competing Program; provided further that such Party shall terminate, and shall cause its Affiliates to terminate, the Competing Program if such Party has not completed such divestment within [***] months after the closing of the Competing Product Transaction. During the divestment period, the applicable Party shall, and shall cause its Affiliates to, (A) segregate the Competing Program from the Collaboration, including, to the extent practicable, by establishing separate teams to conduct Development and Commercialization and (B) use good faith, diligent efforts to prevent any Confidential Information relating to the Collaboration from being disclosed to, or used by, individuals conducting any activities with respect to the Competing Program.

(ii) Termination of Competing Program. In the event that the Party elects to terminate the Competing Program as described in Section 10.6(b), it shall, and shall cause its Affiliates to, promptly (but, in no event, more than [***] months following closing of the Competing Product Transaction), discontinue all Restricted Activities. During the period prior to termination of the Competing Program, the applicable Party shall, and shall cause its Affiliates to, (A) segregate the Competing Program from the Collaboration, including, to the extent practicable, by establishing separate teams to conduct Development and Commercialization and (B) use good faith, diligent efforts to prevent any Confidential Information relating to the Collaboration from being disclosed to, or used by, individuals conducting any activities with respect to the Competing Program.

(iii) Maintaining Competing Program. In the event that TBIL or the Person that acquires TBIL elects to keep the Competing Program as described in Section 10.6(b), then unless otherwise agreed to in writing by Takeda: [***]

(c) Jurisdictional Compliance. It is the desire and intent of the Parties that the restrictive covenants contained in this Section 10.6 be enforced to the fullest extent permissible under the Applicable Laws and public policies applied in each jurisdiction in which enforcement is sought. The Parties believe that such restrictive covenants in this Section 10.6 are valid and enforceable. However, if any such restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent

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necessary in order that such provision be valid and enforceable, such amendment shall apply only with respect to the particular jurisdiction in which such declaration is made.

ARTICLE XI
TRADEMARKS AND CORPORATE LOGOS

11.1 Product Trademarks.

(a) The Product shall be Commercialized exclusively under the Product Trademark(s).

(b) Takeda shall have the sole right, at its discretion, for selecting (including conducting clearance searches for) one or more potential Product Trademarks and shall keep the JSC reasonably informed with respect to the Product Trademarks in the Major Market Countries. For clarity, in no event shall the Product Trademarks include any Housemarks of either Party or any of its Affiliates or any Trademark confusingly similar thereto. Takeda shall own and retain the entire right, title, and interest in Product Trademarks.

(c) Takeda shall have the sole right, at its own expense and discretion, for filing, prosecution, maintenance, defense and enforcement (including, for clarity, any oppositions related thereto) of the Product Trademarks and shall keep the JSC reasonably informed with respect to such activities in the Major Market Countries. Each Product shall be Commercialized pursuant to this Agreement using the Product Trademarks in accordance with the applicable Regulatory Approvals and Applicable Laws.

(d) Takeda shall, and shall cause its Affiliates and Sublicensees to, use each Product Trademark solely to identify the Product in connection with the Commercialization thereof for use in the Field within the Territory, and Takeda shall not (and shall cause its Affiliates and Sublicensees not to) use such Product Trademark to identify any other products or for any other purpose.

11.2 Corporate Names.

(a) Subject to the licenses granted in Section 11.2(b), each Party and its Affiliates shall retain all right, title, and interest in, to, and under their respective corporate names and logos and goodwill related thereto (the "Housemarks"). To the extent permitted or required by Applicable Law, the TBIL Housemarks and the Takeda Housemarks shall be given comparable size and prominence on all Labeling used in connection with Commercialization of the Products under this Agreement and the Parties agree to cooperate as reasonably necessary to obtain any such necessary Regulatory Approvals and to otherwise comply with Applicable Law in connection therewith. In addition, all Labeling, to the extent practicable, shall include a reference (unless prohibited by Applicable Law) to the contribution of the license from TBIL for the Product (for example, by stating "Licensed from THERAVANCE BIOPHARMA IRELAND LIMITED").

(b) TBIL hereby grants to Takeda a non-exclusive, non-transferable, royalty-free license during the Term throughout the Territory to utilize the TBIL Housemarks for use solely in Commercializing the Products hereunder. Takeda shall only use the TBIL Housemarks

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with the necessary trademark designations in a manner that does not derogate from TBIL's rights in its Trademarks. Takeda shall submit representative samples of its proposed use of the TBIL Housemarks for review by the JSC reasonably in advance of the use to permit the JSC to consider and comment upon such proposal. Takeda acknowledges the goodwill and reputation that has been associated with the TBIL Housemarks, and subject to the terms hereof, shall use such Housemarks in a manner that maintains and promotes such goodwill and reputation and is consistent with trademark guidelines provided by TBIL to Takeda from time to time, to the extent in compliance with Applicable Laws. Takeda shall take all reasonable precautions and actions to protect the goodwill and reputation that has inured to the TBIL Housemarks, and to take no action that may interfere with or diminish the rights of TBIL in its Housemarks. Takeda agrees that all use of the TBIL Housemarks will inure to the benefit of TBIL, including all goodwill in connection therewith.

ARTICLE XII
OWNERSHIP OF DATA, PATENTS AND INVENTIONS

12.1 Ownership of Existing Intellectual Property. Subject to the licenses granted in Article III, as between the Parties: (a) TBIL is and shall remain the sole and exclusive owner of all right, title, and interest in, to and under the TBIL Technology and all other Intellectual Property owned by TBIL or its Affiliates as of the Effective Date, and (b) Takeda is and shall remain the sole and exclusive owner of all right, title, and interest in, to and under the Takeda Technology, and any other Intellectual Property owned by Takeda or its Affiliates as of the Effective Date.

12.2 Know-How Developed During the Term. Inventorship shall be determined in accordance with U.S. patent law. Each Party shall own and retain the entire right, title, and interest in, to, and under all Know-How invented during the Term solely by or on behalf of such Party or any of its Affiliates. In the event any Know-How is invented jointly by the Parties during the Term, each Party will jointly own such Know-How ("Joint Know-How"). Subject to any licenses granted under this Agreement, each Party will have the right to practice and exploit any Joint Know-How without the duty of accounting to the other Party or seeking consent (for licensing, assigning or otherwise exploiting Joint Know-How) from the other Party by reason of the joint ownership thereof; and each Party hereby waives any right such Party may have under the Applicable Law of any jurisdiction to require any such approval or accounting, and, to the extent Applicable Law prohibits such a waiver, each Party shall be deemed to so consent. In furtherance thereof, at the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Know-How. Each Party shall, before the first filing of a new Patent application claiming or disclosing any Joint Know-How, promptly disclose such proposed Patent application to the other Party, provided, that, to the extent such Patent Covers a Compound or Product, such Patent shall be deemed a Takeda Patent for the purposes of Section 8.3(b) and this Article XII.

(a) Each Party shall, before the first filing of a new application claiming or disclosing any Technology, promptly disclose such Technology to the other Party.

(b) Each Party shall use Commercially Reasonable Efforts to obtain an assignment from each of its of its Sublicensees and Subcontractors of all Know-How invented by

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such Sublicensee or Subcontractor that relates to one or more Products, and if such Party cannot obtain such assignment from any such Sublicensee or Subcontractor, a license (either exclusive or non-exclusive as appropriate depending on the type of technology but with the goal of maximizing the intellectual property protection of such Party) with the right to grant a sublicense to the other Party in the applicable scope as provided in this Agreement.

(c) In the event that the Parties disagree as to whether Technology is owned by Takeda or TBIL, and are unable to reach agreement within thirty (30) days after commencing discussions, then the provisions of Section 16.1(a) and Section 16.1(c) shall apply to such dispute.

12.3 Preparation, Prosecution and Maintenance of Patents.

(a) TBIL Patents. As between the Parties, and subject to Section 12.3(c), TBIL shall have the exclusive right (but not the obligation) to prepare, file, prosecute (including by conducting interferences, oppositions, inter partes reviews, nullity actions, and reexaminations or other similar proceedings, but subject to Section 12.4(a)), maintain (including by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under Applicable Laws) and extend all TBIL Patents (such activities, collectively, the "Prosecution Activities").

(b) Takeda Patents. As between the Parties, and subject to Section 12.3(c), Takeda shall have the exclusive right (but not the obligation) to perform the Prosecution Activities for all Takeda Patents.

(c) Cooperation. TBIL (with respect to the TBIL Patents) and Takeda (with respect to the Takeda Patents Covering a Product) (each of TBIL and Takeda in such circumstances, the "Prosecuting Party") shall keep the other Party (the "Non-Prosecuting Party") reasonably informed regarding the status of the Prosecution Activities that it is conducting in accordance with Section 12.3(a) or Section 12.3(b), as applicable, and, at the Non-Prosecuting Party's request, shall provide the Non-Prosecuting Party with copies of all documentation concerning the applicable Patents, including all correspondence to and from any Governmental Authority relating thereto. Upon the Non-Prosecuting Party's request, prior to filing Patent applications for, or material prosecution documents or other submissions relating to, the Patents for which the Prosecuting Party is responsible, the Prosecuting Party shall provide the Non-Prosecuting Party with a reasonable opportunity to review and comment on the proposed application, document or submission, and the Prosecuting Party shall reasonably consider all such comments of the Non-Prosecuting Party, unless (without fault of the Prosecuting Party) deadlines will not permit such review. For clarity, in the event of a dispute between the Parties regarding the content of any such applications, documents, or submissions, the Prosecuting Party shall have the final decision-making authority with respect thereto.

(d) Abandonment. In the event that (i) TBIL (as the Prosecuting Party) elects to abandon the prosecution of a TBIL Patent application or maintenance of an issued TBIL Patent, or (ii) Takeda (as the Prosecuting Party) elects to abandon the prosecution of a Takeda Patent application or maintenance of an issued Takeda Patent Covering a Product, such Prosecuting Party shall notify the Non-Prosecuting Party in writing (such notice, an

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"Abandonment Notice") at least [***] days prior to any filing or payment due date or any other due date that requires action to prevent such loss of rights, and in the event that the Non-Prosecuting Party provides the Prosecuting Party with written notice within [***] days of receipt of the applicable Abandonment Notice, the Non-Prosecuting Party shall thereafter have the right, at its sole expense, (i) to be assigned the right, title and interest in, to and under the applicable Patent (and following such assignment, notwithstanding anything to the contrary herein, such Patent shall no longer be a TBIL Patent or a Takeda Patent, as applicable, for the purposes of this Article XII or Section 8.3(b), and (ii) following such assignment, to conduct such Prosecution Activities for the applicable Patent. For the avoidance of doubt, if the Parties agree that a Patent should be abandoned for strategic reasons, this Section 12.3(d) shall not apply to such abandoned Patent.

(e) Cooperation. The Non-Prosecuting Party shall provide the Prosecuting Party all reasonable assistance and cooperation, at the Non-Prosecuting Party's request and expense, in connection with the Prosecution Activities, including by furnishing all information and data in its Control reasonably necessary to prepare, file, prosecute, maintain, or extend any Patents hereunder.

(f) Expenses. Each Party shall be solely responsible for its internal expenses incurred in furtherance of the Prosecution Activities. Takeda shall be responsible for Third Party Expenses incurred by or on behalf of itself in connection with Prosecution Activities for the Takeda Patents in the Territory. Takeda shall reimburse TBIL for fifty percent (50%) of TBIL's or its Affiliates' Third Party Expenses reasonably incurred in furtherance of the Prosecution Activities for the TBIL Patents, subject to an annual budget for such Prosecution Activities to be agreed to by the Parties. Takeda shall reimburse TBIL in accordance with Section 8.6.

(g) Patent Term Extensions. Through the JSC, the Parties shall cooperate to determine the TBIL Patents and Takeda Patents for which to seek extensions (including supplementary protection certificates), with, for clarity, Takeda having final decision-making authority with respect to such decision. Following such determination, the Prosecuting Party shall be responsible for using Commercially Reasonable Efforts to obtain all such extensions.

(h) Regulatory Patent Listing. Takeda shall be solely responsible for: (i) filing appropriate information with the FDA in the U.S. listing any TBIL Patents and Takeda Patents in the Orange Book; and (ii) with respect to other countries in the Territory, filing appropriate information with the applicable Regulatory Authority listing any TBIL Patents and Takeda Patents in the Patent listing source in such country in the Territory that is equivalent to the Orange Book, if any. Upon the reasonable request of Takeda, TBIL shall reasonably assist Takeda with its efforts in filing the appropriate information to have a TBIL Patent listed in the Orange Book or its equivalent, and Takeda shall reimburse TBIL for fifty percent (50%) of its and its Affiliates' Third Party Expenses incurred to conduct such assistance requested by Takeda. Takeda shall provide TBIL with a reasonable opportunity to review and comment (which Takeda shall reasonably consider in good faith) on the information proposed for submission with respect to a TBIL Patent or Takeda Patent that Covers any Products.

(i) Registration of Exclusive License. Upon Takeda's reasonable request, TBIL shall register before any appropriate Governmental Authority in the Territory that Takeda

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is the exclusive licensee under the TBIL Patents. Takeda shall reimburse TBIL for fifty percent (50%) of its and its Affiliates' Third Party Expenses incurred in connection with any registration requested by Takeda under this Section 12.3(i).

12.4 Patent Infringement.

(a) Notification. Each Party shall promptly notify the other Party in writing (each such notice, an "Infringement Notice") of any actual or threatened infringement, misappropriation, or other violation or challenge to the validity, scope, or enforceability of any TBIL Technology or Takeda Technology in the Field within the Territory of which it becomes aware, including, for clarity, any Paragraph IV Notices ("Third Party Infringement"). For clarity, any challenge to the validity, scope or enforceability of any TBIL Patent in connection with an actual or threatened infringement of such Patent shall be governed by this Section 12.4 and not Section 12.3.

(b) Third Party Infringement. In the event of any Third Party Infringement, Takeda will have the first right (but not the obligation) with respect to TBIL Technology, and sole right (but not the obligation) with respect to the Takeda Technology, to bring, enforce or defend entirely under its own direction and control an action, suit, claim, arbitration, or proceeding regarding, or otherwise seek to obtain agreement from the alleged infringer to desist, such Third Party Infringement (each, an "Infringement Action"). If Takeda elects to pursue an Infringement Action, Takeda shall be solely responsible for expenses it incurs in connection with such Infringement Action. In the event that Takeda fails to initiate an Infringement Action with respect to the TBIL Technology (or otherwise does not [***]) within the earlier of (i) [***] days after receipt of the Infringement Notice, or (ii) [***] days before the expiration date for filing such Infringement Action or responding (as applicable), TBIL shall be permitted to initiate an Infringement Action with respect to the TBIL Technology (but not any Takeda Technology) at its sole expense. Notwithstanding the foregoing, in the event that the Party who is not bringing the applicable Infringement Action (the "Non-Controlling Party") recommends that the other Party not pursue the applicable Infringement Action, the other Party (the "Controlling Party") shall reasonably consider such recommendation in good faith.

(c) Assistance. The Controlling Party shall keep the Non-Controlling Party reasonably informed about the status of each Infringement Action and consult with the Non-Controlling Party regarding material aspects of each Infringement Action and take any comments it receives into consideration in good faith. At the request of the Controlling Party, the Non-Controlling Party and its Affiliates shall provide reasonable assistance in connection with any Third Party Infringement, including by joining in any such Infringement Action and executing all papers and performing such other acts as may be reasonably necessary to permit the Controlling Party to commence or prosecute such Infringement Action (which, for clarity, shall include allowing the Controlling Party to bring any Infringement Action in the name of the Non-Controlling Party or any of its Affiliates to the extent required to maintain standing). Except as otherwise provided herein, the Controlling Party shall reimburse the Non-Controlling Party for any reasonable Third Party Expenses incurred in providing such assistance. The Non-Controlling Party shall have the right to be represented in any such Infringement Action in which it is a party by independent counsel (which shall act in an advisory capacity only, except for matters solely directed to such Party) of its own choice and at its own expense. If the Non-

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Controlling Party in any such Infringement Action is a party to such Infringement Action, such Non-Controlling Party may request that the Parties be jointly represented by the same outside counsel. The Controlling Party shall have the right to withhold consent to such joint representation of the Parties. Notwithstanding anything to the contrary in this Section 12.4(c), if the counsel of the Controlling Party reasonably determines that the Non-Controlling Party is required to join an Infringement Action brought hereunder in connection with a Third Party Infringement to maintain standing, such Party shall so join such Infringement Action, the Controlling Party shall reimburse all reasonable Third Party Expenses incurred by the Non-Controlling Party in connection with such Infringement Action.

(d) Settlements. The Controlling Party shall give the Non-Controlling Party timely notice of any proposed settlement of any Infringement Action instituted by the Controlling Party to enforce the TBIL Technology or the Takeda Technology and shall not, without the prior written consent of such Non-Controlling Party (not to be unreasonably withheld, conditioned or delayed), enter into any settlement that would: adversely affect the validity, enforceability, or scope of, or admit non-infringement of, any Patents that the Non-Controlling Party owns or to which the Non-Controlling Party is granted a license or other rights, give rise to liability of such Non-Controlling Party, its Affiliates, or its or their licensors, licensees or Sublicensees (to the extent applicable), grant to a Third Party a license or covenant not to sue under any Intellectual Property that the Non-Controlling Party owns or to which the Non-Controlling Party is granted a license or other rights, or otherwise impair such Non-Controlling Party's and its Affiliates' rights in, to, or under any Intellectual Property.

(e) Recoveries. If the Controlling Party brings an Infringement Action to enforce any TBIL Technology or Takeda Technology and any sums are recovered in connection therewith, the Controlling Party shall first reimburse itself, and then reimburse the Non-Controlling Party (to the extent applicable), out of any sums recovered in such action, suit, claim, arbitration, or proceeding, or in the settlement thereof, for all reasonable Third Party Expenses, including attorneys' fees paid, incurred in connection with such Infringement Action, and with respect to the balance of such sums: (i) if Takeda is the Controlling Party, such balance shall be treated as Net Sales for which Royalties are payable hereunder and (ii) if TBIL is the Controlling Party, such balance shall be allocated eighty percent (80%) to TBIL and twenty percent (20%) to Takeda. Notwithstanding the foregoing (except with respect to the obligation to reimburse Third Party Expenses), Takeda shall retain all sums recovered in connection with the enforcement of the Takeda Patents to the extent the Patents included therein (if any) do not Cover any Compounds or Products.

12.5 Infringement of Third Party Patents. Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that Intellectual Property owned or otherwise controlled by such Third Party is infringed, misappropriated, or otherwise violated by the Development, Commercialization or other Exploitation of any Product in the Field in any country in the Territory, of which it becomes aware. Subject to any indemnification obligations of a Party to the other Party under Article XIV, each Party shall have the first right, but not the obligation, to defend any such Third Party claim brought against it, at its expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of such claim, including, if required to conduct such defense, furnishing a power of attorney. Neither Party shall enter into any settlement of any such claim under this Section 12.5 that affects the other

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Party's rights or interests without such other Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. Each Party shall have the right to decline to defend, or to tender the defense of, any such claim under this Section 12.5 upon reasonable written notice to the other Party, including if the other Party fails to agree to a settlement that the declining Party proposes. Any settlement or license fees incurred by a Party under this Section 12.5 shall be subject to the terms of Section 8.4.

ARTICLE XIII
PATENT MARKING

13.1 Patent Marking. Takeda shall, and shall cause its Affiliates and Sublicensees to, mark Products sold by, or on behalf of, Takeda, its Affiliates, and its Sublicensees hereunder (in a reasonable manner consistent with Takeda's custom and practice, including by use of other substantially equivalent ways of providing notice under any Applicable Law) with appropriate patent numbers or indicia to the extent permitted by Applicable Law, in those countries or regulatory jurisdictions in the Territory in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements or other violations of any patent rights.

ARTICLE XIV
INDEMNIFICATION; INSURANCE

14.1 Indemnification by TBIL. TBIL hereby agrees to save, indemnify, defend and hold harmless Takeda, its Affiliates, and each of their respective directors, officers, shareholders, agents, employees, successors and assigns (each, a "Takeda Indemnitee") from and against any and all losses, damages, liabilities, expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each, a "Third Party Claim") to the extent that any Third Party Claim arises out of (a) any breach by TBIL of any of its representations, warranties or covenants under this Agreement, (b) TBIL's, its Affiliates' or their respective licensees', sublicensees' or Subcontractors' fraud, negligence or willful misconduct, (c) any Manufacture, Development or other Exploitation of the Compounds or Products by or on behalf of TBIL, its Affiliates, or their respective licensees, sublicensees or Subcontractors both before the Effective Date and after the Effective Date; or (d) any Manufacture, Development or other Exploitation of any Products in a Terminated Country by or on behalf of TBIL, its Affiliates, or their respective licensees, sublicensees, Subcontractors and/or Designees; in each case except to the extent that such Losses arise or result from any Takeda Indemnitee's fraud, gross negligence, willful misconduct or material breach of this Agreement.

14.2 Indemnification by Takeda. Takeda hereby agrees to save, indemnify, defend and hold harmless TBIL, its Affiliates, and each of their respective directors, officers, shareholders, agents, employees, successors and assigns (each, a "TBIL Indemnitee") from and against any and all Losses arising in connection with any and all Third Party Claims arising out of (a) any breach by Takeda of any of its representations, warranties or covenants under this Agreement, (b) Takeda's, its Affiliates' or their respective licensees', Sublicensees' or Subcontractors' fraud, negligence or willful misconduct, or (c) any Manufacture, Development,

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Commercialization or other Exploitation of the Products by or on behalf of Takeda, its Affiliates, or their respective licensees, its Sublicensees or Subcontractors; in each case except to the extent that such Losses arise or result from any TBIL Indemnitee's fraud, gross negligence, willful misconduct or material breach of this Agreement.

14.3 Indemnity Procedure.

(a) If a TBIL Indemnitee or Takeda Indemnitee (each, an "Indemnified Party") shall receive notice or otherwise learn of the assertion or commencement of any Third Party Claim with respect to which Takeda or TBIL, respectively, (each, the "Indemnifying Party") may be obligated to provide indemnification to such Indemnified Party pursuant to Section 14.1 or Section 14.2, or any other section of this Agreement, such Indemnified Party shall give such Indemnifying Party written notice thereof clearly stating such Third Party Claim and identifying the Indemnified Party seeking indemnification hereunder ("Indemnification Notice") as promptly as practicable (and in any event within forty-five (45) Business Days) after becoming aware of such Third Party Claim. Any such notice shall describe the Third Party Claim in reasonable detail. Notwithstanding the foregoing, the failure of any Indemnified Party or other Person to give an Indemnification Notice shall not relieve the related Indemnifying Party of its obligations under this Article XIV, except to the extent, and only to the extent, that such Indemnifying Party is materially prejudiced by such failure to give notice.

(b) An Indemnifying Party may elect (but shall not be required) to defend, at such Indemnifying Party's own expense and by such Indemnifying Party's own counsel (which counsel shall be reasonably satisfactory to the Indemnified Party), any Third Party Claim; provided that the Indemnifying Party shall not be entitled to defend and shall pay the reasonable fees and expenses of one separate counsel for any Indemnified Parties if the claim for indemnification relates to or arises in connection with any criminal action, indictment or allegation. Within forty-five (45) Business Days after the receipt of an Indemnification Notice (or sooner, if the nature of such Third Party Claim so requires), the Indemnifying Party shall notify the Indemnified Party of its election whether the Indemnifying Party will assume responsibility for defending such Third Party Claim, which election shall specify any reservations or exceptions to its defense. After notice from an Indemnifying Party to an Indemnified Party of its election to assume the defense of a Third Party Claim, such Indemnified Party shall have the right to employ separate counsel and to participate in (but not control) the defense, compromise, or settlement thereof, but the fees and expenses of such counsel shall be the expense of such Indemnified Party; provided, however, that in the event that the Indemnifying Party has elected to assume the defense of the Third Party Claim but has specified, and continues to assert, any reservations or exceptions in such notice, the reasonable fees and expenses to the extent related to such matters of one separate counsel for all Indemnified Parties shall be borne by the Indemnifying Party.

(c) If an Indemnifying Party elects not to assume responsibility for defending a Third Party Claim, or fails to notify an Indemnified Party of its election as provided in Section 14.3(b), such Indemnified Party may defend such Third Party Claim at the sole expense of the Indemnifying Party. Any reasonable legal fees and expenses incurred by the Indemnified Party in connection with defending such claim shall be paid by the Indemnifying Party at the then applicable regular rates charged by counsel to the Indemnified Party.

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(d) Unless the Indemnifying Party has failed to assume the defense of the Third Party Claim in accordance with the terms of this Agreement, no Indemnified Party may settle or compromise any Third Party Claim without the prior written consent of the Indemnifying Party. If an Indemnifying Party has failed to assume the defense of the Third Party Claim within the time period specified in Section 14.3(b) above, absent any bona fide dispute as to whether such Third Party Claim is subject to such Indemnifying Party's indemnification obligations for which such Indemnifying Party is successful, it shall not be a defense to any obligation to pay any amount in respect of such Third Party Claim that the Indemnifying Party was not consulted in the defense thereof, that such Indemnifying Party's views or opinions as to the conduct of such defense were not accepted or adopted, that such Indemnifying Party does not approve of the quality or manner of the defense thereof or that such Third Party Claim was incurred by reason of a settlement rather than by a judgment or other determination of liability.

(e) In the case of a Third Party Claim, no Indemnifying Party shall consent to entry of any judgment or enter into any settlement of the Third Party Claim without the prior written consent of the Indemnified Party if the effect thereof is (i) to permit any injunction, declaratory judgment, other order or other non-monetary relief to be entered, directly or indirectly, against any Indemnified Party or (ii) to ascribe any fault on any Indemnified Party in connection with such defense. If the Indemnifying Party assumes the defense of the Third Party Claim, and the Third Party Claim concerns Intellectual Property owned by the other Party or any of its Affiliates, or to which such other Party or any of its Affiliates have rights, the Indemnifying Party shall reasonably cooperate with such other Party with respect to such aspects of the Third Party Claim that concern the ownership, validity, enforceability, or scope of such Intellectual Property, including by not making any admission or offer of settlement in such Third Party Claim that could reasonably be expected to have any prejudice or adverse effect with respect thereto or that grants a license, covenant not to sue or other rights with respect to such Intellectual Property. Notwithstanding anything to the contrary herein, the Indemnifying Party shall not, without the prior written consent of the Indemnified Party, settle or compromise any Third Party Claim or consent to the entry of any judgment which does not include as an unconditional term thereof the delivery by the claimant or plaintiff to the Indemnified Party of a written release from all liability in respect of such Third Party Claim.

14.4 Certain Limitations on Liability.

(a) The Parties intend that any Loss subject to indemnification or reimbursement pursuant to Article XIV will be net of insurance proceeds that actually reduce the amount of the Loss. Accordingly, the amount which any Indemnifying Party is required to pay to any Indemnified Party will be reduced by any insurance proceeds theretofore actually recovered by or on behalf of the Indemnified Party in respect of the related Loss. If an Indemnified Party receives a payment required by this Agreement from an Indemnifying Party in respect of any Loss (an "Indemnity Payment") and subsequently receives insurance proceeds, then the Indemnified Party will reimburse to the Indemnifying Party an amount equal to the excess of the Indemnity Payment received over the amount of the Indemnity Payment that would have been due if the insurance proceeds had been received, realized or recovered before the Indemnity Payment was made.

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(b) An insurer who would otherwise be obligated to pay any claim shall not be relieved of the responsibility with respect thereto or, solely by virtue of the indemnification provisions hereof, have any subrogation rights with respect thereto, it being expressly understood and agreed that no insurer or any other Third Party shall be entitled to a "wind-fall" (i.e., a benefit such insurer or other Third Party would not be entitled to receive in the absence of the indemnification provisions) by virtue of the indemnification provisions hereof. Nothing contained in this Agreement shall obligate any Person to seek to collect or recover any insurance proceeds.

14.5 Insurance. Each Party shall, at its own expense, procure and maintain during the Term and for a period of five (5) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this Article XIV. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within thirty (30) days after any such cancellation, non-renewal or material change. The Parties acknowledge and agree that Takeda may meet its obligations under this Section 14.5 through self-insurance.

ARTICLE XV
TERM AND TERMINATION

15.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article XV, shall remain in effect on a country-by-country basis or in its entirety until the date on which the Royalty Term expires for such Product in such country (the "Term"), whereupon the license granted to Takeda under Section 3.1 shall become non-exclusive, fully-paid, royalty-free, perpetual and irrevocable.

15.2 Termination Based on Mutual Written Agreement. This Agreement may terminate on a Product-by-Product and country-by-country basis upon mutual written agreement of the Parties.

15.3 Termination for Material Breach. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in its entirety in the event that the other Party is in material breach of this Agreement and fails to cure such breach (in the case of Takeda, including any Shelving Breach) within [***] days (thirty (30) days in the event of breaches related to payment obligations) of receiving written notice from the other Party expressly putting such Party on notice of the allegation of such material breach ("Notice Period"). Any failure to timely notify under Sections 4.6, 6.1 or 6.3 will not be deemed a material breach of this Agreement unless all such applicable failures, in the aggregate, have a material adverse effect on the Development or Commercialization of the Products or the other Party's rights under this Agreement. Notwithstanding the foregoing, if such material breach is incapable of being cured within the Notice Period, then the non-breaching Party's right of termination shall be suspended only if, and for so long as, the other Party has provided to the non-breaching Party and is diligently implementing a written plan that is reasonably calculated to effect a cure of such material breach in as prompt a manner as is reasonably practical; provided

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that, the non-breaching Party's right of termination shall not in any case be suspended any longer than an additional [***] days following the unextended expiration of the Notice Period. In addition and notwithstanding the foregoing, if the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party that disputes whether there has been a material breach may contest the allegation in accordance with Section 16.1(b), and such Notice Period shall not commence unless and until the final conclusion of such dispute determining the existence of such material breach. During such dispute, all of the terms and conditions of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations under this Agreement.

15.4 Termination For Insolvency or Bankruptcy. Each Party shall have the right to terminate this Agreement upon written notice in the event that the other Party (a) commences, or has commenced against it, bankruptcy proceedings in any jurisdiction and such proceedings are not dismissed within [***] days after the filing thereof, (b) makes a general assignment for the benefit of its creditors, (c) becomes insolvent, (d) has a receiver appointed for it or its business, (e) ceases operations, or (f) is liquidated or dissolved, in each case unless such situation has been withdrawn, reverted and/or dismissed during such [***]-day notice period.

15.5 Termination by Takeda For Convenience. Takeda shall have the right to terminate this Agreement in its entirety or on a country-by-country basis, for convenience: (a) upon providing TBIL with [***] days' prior written notice if such termination is [***] for such Product in such country; and (b) upon providing TBIL with [***] days' prior written notice if such termination is [***] for such Product in such country.

15.6 Termination for Safety Reasons. Takeda shall have the right to terminate this Agreement for Safety Reasons, upon [***] days' prior written notice to TBIL, which notice shall set forth, in reasonable detail, the applicable Safety Reason(s) and shall include reasonably detailed documentation supporting the existence of such Safety Reason; provided that [***], and shall provide [***]. Takeda shall have the right to wind down and/or suspend all Development and/or Commercialization activities during such notice period.

15.7 Termination for Failure to Advance the Program. Without prejudice to any other remedies available to it at law or in equity (including for any breach of the terms hereof), in the event Takeda is not conducting any ongoing Development and/or Commercialization activities (including related Manufacturing activities) for at least [***], and such lack of activity: (i) is not [***], (ii) is not a result of [***] (a "Shelving Breach"), then such lack of activity will be deemed a material breach of this Agreement, TBIL shall have the right to provide written notice to Takeda for such Shelving Breach under Section 15.3, and the terms of Section 15.3 (including cure periods) will apply.

15.8 Effects of Termination. Termination for Reasons Other than TBIL's Breach or Insolvency. Upon any termination (but not expiration) of this Agreement pursuant to Section 15.2 by mutual written agreement, by TBIL pursuant to Section 15.3, Section 15.4 or Section 15.7 for Takeda's material breach, bankruptcy or Shelving Breach, respectively, or by Takeda pursuant to Section 15.5 or Section 15.6, for convenience, Safety Reasons, respectively, the following, unless otherwise noted herein, shall apply as of the effective date of such termination:

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(i) Country-by-Country Termination. For clarity, in the event that this Agreement has been terminated with respect to a particular country (such country, a "Terminated Country") (and not this Agreement in its entirety) to the extent permitted hereunder, notwithstanding anything to the contrary herein, such Terminated Country shall no longer be deemed a part of the Territory for such Terminated Product as of the effective date of such termination and the provisions set forth in this Section 15.8(a) shall only apply with respect to such Terminated Country. For clarity, in the event that this Agreement is terminated in its entirety, the entire Territory shall be deemed to be the Terminated Countries, and the provisions set forth in this Section 15.8(a) shall apply to such Terminated Countries.

(ii) Licenses to Takeda. All rights and licenses granted to Takeda hereunder with respect to the Products in the Terminated Countries shall immediately terminate and be of no further force and effect, and Takeda shall cease Developing, Commercializing and otherwise Exploiting the Products in the Terminated Countries (except as otherwise set forth in this Section 15.8) and using any and all TBIL Technology for Products in the Terminated Countries, except, in each case, to the extent necessary to effect an orderly transition in accordance with the terms hereof or as otherwise expressly set forth herein.

(iii) Regulatory Materials, Regulatory Approvals, and Information. To the extent permitted by Applicable Law, Takeda shall: (A) provide to TBIL a copy of all Regulatory Materials to the extent related to the Products in the Terminated Countries that are in Takeda's possession; or (B) to the extent such Regulatory Materials are not in Takeda's possession, grant TBIL the same right to access and reference such Regulatory Materials as held by Takeda prior to the effective date of such termination. In addition, to the extent permitted by Applicable Law, Takeda shall transfer and assign (and where applicable, shall cause its Affiliates and Sublicensees to transfer and assign) to TBIL all INDs and Regulatory Approvals related solely to the Products in the Terminated Countries; provided that, until such transfer and assignment is effected or in the event that any of the foregoing cannot be so transferred and assigned pursuant to Applicable Law, and with respect to Regulatory Materials that are reasonably required for TBIL to Develop, Commercialize and/or otherwise Exploit a Product in the Terminated Countries, TBIL (and its Designee, as applicable) shall have the right to access, use and cross-reference such Regulatory Materials solely for the purpose of Exploiting such Products in such Terminated Countries. Takeda hereby grants any consent (and where applicable, shall cause its Affiliates and Sublicensees to so consent) solely to the extent necessary to permit TBIL (and its Designee, as applicable) to exercise such rights. In addition, subject to and in accordance with Section 6.6(b), Takeda shall provide to TBIL copies of inspection or audit observations of Regulatory Authorities and any written responses thereto.

(iv) License to TBIL. Takeda hereby grants and shall cause its Affiliates to grant to TBIL, effective on the effective date of termination, on reasonable terms and conditions to be agreed by the Parties in good faith, (but which in any case, will be customary in the industry for licenses granted under product reversion circumstances), an exclusive (including as to Takeda and its Affiliates), limited, sublicensable, royalty-bearing license under (A) the Takeda Technology in existence as of the effective date of termination and that is incorporated by or on behalf of Takeda, its Affiliates or its Sublicensees into, or actually used by or on behalf of Takeda, its Affiliates or its Sublicensees in connection with, the Products in the Terminated Countries, solely to Exploit the Products in the Terminated

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Countries; and (B) the Product Trademarks selected for use with any Products in the Terminated Countries in connection with TBIL's exercise of its licenses under subsection (A). For clarity, the foregoing licenses shall include rights to improve or otherwise modify the Products, but the license granted by Takeda to TBIL in this Section 15.8(a)(iv) shall not include the right to incorporate any Takeda Technology in any product (in or outside of a Terminated Country) that is not a Product that arises from any such post-termination modification, unless the Parties otherwise agree as part of such license. The Parties shall, exercising good faith, take all actions reasonably necessary to enter into a license agreement that reflects such terms promptly, but in no event more than [***] days, following the effective date of termination. If the Parties comply with such obligations to negotiate in good faith, and endeavor to agree upon, the terms of such license agreement, but fail to agree upon such terms within the [***] day negotiation period, any dispute shall be resolved in accordance with Sections 16.1(a) and 16.1(c) and upon resolution of such dispute, the Parties shall automatically enter into the license agreement, as formulated through that process, as of the date of such resolution and the license shall be effective as of the effective date of termination.

(v) Ongoing Clinical Trials.

(1) In the event this Agreement is terminated by Takeda in a Major Market Country or its entirety pursuant to Section 15.5 (Termination for Convenience) or TBIL terminates this Agreement pursuant to Section 15.3 (Termination for Material Breach) and [***] that is the subject of such termination, Takeda shall: upon TBIL's written request and in TBIL's sole discretion, (A) [***] or (B) [***] and (C)(1) [***]; or (C) (2) [***]. In the event TBIL does not request either (i) [***] then Takeda shall instead [***]. If requested by TBIL, Takeda shall provide [***] of notice of termination.

(2) In the event that this Agreement is terminated by Takeda in a Major Market Country or in its entirety by the Parties pursuant to Section 15.2 or by TBIL pursuant to Section 15.4 or 15.7 and that are [***], and upon TBIL's written request, Takeda shall (i) [***], shall be solely borne by TBIL; or (ii) [***]. If requested by TBIL, Takeda shall provide [***] months prior to receipt of notice of termination.

(vi) Adverse Event Reporting and Safety Data Exchange.

(1) During the period commencing on receipt of written notice of termination (or agreement to terminate if termination is pursuant to Section 15.2) until the transition activities contemplated in this Section 15.8(a) are complete, Takeda shall, in accordance with all Applicable Laws, be responsible for monitoring all clinical experiences, maintaining the global safety database, safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities in the Terminated Countries with respect to the Products, including annual safety reports. In the event this Agreement is terminated in its entirety or the U.S. is a Terminated Country, Takeda shall transfer to TBIL (or its Designee) the global safety database for the Products; provided, that, in all other circumstances, the Parties shall discuss whether the global safety base should be transferred to TBIL or retained by Takeda. Notwithstanding the foregoing, the Parties shall enter into a new (or amend the current) PVA within [***] days after the effective date of termination to govern the exchange of safety data between the Parties with respect to Products in the Terminated

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Countries, and upon effectiveness thereof, such agreement will supersede the terms of this Section 15.8(a)(vi)(i).

(2) In the event the global safety database is transferred to TBIL, at the time of transfer, Takeda shall confirm in writing that all safety data related to the Products is accurately reflected in the global safety database then-existing and being maintained by Takeda. Until such time as the global safety database is transferred to TBIL hereunder and thereafter in the event Takeda receives any safety updates, Takeda shall prepare and provide to TBIL on a timely basis any safety updates received by or on behalf of Takeda or any of its Affiliates, Sublicensees and/or Subcontractors; provided that in no case shall the exchange of information related to adverse events occur later than [***] days for any fatality and/or life-threatening safety event, [***] days for other related serious adverse events, and [***] days for other, non-serious adverse events.

(vii) Technology Transfer. Takeda shall transfer to TBIL (or its Designee) the then-current Manufacturing processes, as well as any other Takeda Know-How with respect to the Products in the Terminated Countries, solely for TBIL to Develop, Manufacture, Commercialize and otherwise Exploit the Products in the Terminated Countries. Except in the event any grounds of such termination are in dispute, upon TBIL's reasonable request, the Parties shall commence the transfer of any such Manufacturing processes during the termination notice period (if applicable).

(viii) Inventory. In the event this Agreement is terminated in its entirety for any reason other than upon Takeda's termination pursuant to Section 15.6 (Termination for Safety Reasons), TBIL shall have the right to purchase from Takeda any and all of the inventory of Products (including all bulk drug substance contained therein and any raw materials and/or work-in-progress purchased or produced therefor) held by Takeda as of the effective date of termination at a price equal to (i) [***]. TBIL shall notify Takeda at least [***] days prior to the effective date of termination whether TBIL elects to exercise such right (unless termination is pursuant to Section 15.2, in which event TBIL shall notify Takeda no later than [***] days following the Parties' agreement to terminate) and in the event that TBIL exercises such right, upon payment of such expense therefor, Takeda shall promptly transfer such inventory to TBIL (or its Designee). In the event TBIL does not exercise such right and the Product(s) is being Commercialized in the Terminated Country(ies), then Takeda shall have the right to continue to sell the inventory of such Products for a period of up to [***] months after the effective date of such termination. Notwithstanding the foregoing, if the termination is only effective in certain countries in the Territory, Takeda shall only be required to sell to TBIL the amount of its inventory of the Product that was Manufactured specifically for the Terminated Countries and which would be required to be re-worked (including re-packaged) for use outside of the Terminated Country. To the extent Takeda transfers any inventory of TBIL Products to TBIL under this Section 15.8(a)(viii) as inventory manufactured in compliance with GMP requirements, Takeda shall provide TBIL the applicable documentation required for TBIL to conduct its final release for such inventory in accordance with GMP requirements.

(ix) Manufacture and Supply. Other than Takeda's termination of this Agreement pursuant to Section 15.6 (Termination for Safety Reasons), at TBIL's request,

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Takeda shall supply, or cause to be supplied, to TBIL or its Designee the Products until the earlier of the date TBIL is able to Manufacture or have Manufactured the Products or the end of the first [***] month period following the effective date of termination. Such supply shall be at a price (A) during the first [***] months of such period, equal to [***] and (B) [***].

(x) Third Party Agreements. Upon TBIL's request, Takeda shall, and shall cause its Affiliates to, assign to TBIL (or its Designee) any agreements or arrangements with Third Party vendors to Develop, Manufacture, distribute, sell or otherwise Commercialize or otherwise Exploit any Products, which agreements or arrangements relate solely to the Products in the Terminated Countries. On a country-by country-basis, in the event of termination under Section 15.2 (Termination Based on Mutual Written Agreement) or termination by TBIL under Section 15.3 (Termination for Material Breach), Section 15.4 (Termination for Insolvency or Bankruptcy), or Section 15.7 (Termination for Failure to Advance the Program), (A) [***], and (B) [***]. To the extent that any such agreement between Takeda and a Third Party is not assignable to TBIL (or its Designee, as applicable) or is not related solely to the Products in the Terminated Countries, Takeda shall reasonably cooperate with TBIL for TBIL (or its Designee) to enter into a direct agreement with such Third Party for such services and TBIL shall have no responsibility to reimburse Takeda for Third Party Fees.

(xi) Medical and Consumer Inquiries. If, after the effective date of termination, Takeda receives medical questions or inquiries from members of the medical and paramedical professions or consumers regarding any Product in any Terminated Country, it shall (unless otherwise required by Applicable Law) refer such questions to TBIL (or its Designee), and TBIL (or its Designee) shall be responsible for responding thereto.

(xii) Timing and Diligence. Each Party shall exercise Commercially Reasonable Efforts to complete the transition activities contemplated in this Section 15.8(a) in a timely and efficient manner and as soon as reasonably practicable, and in any event within [***] months after the effective date of termination (or such longer period as the Parties agree in writing or as otherwise specified herein). Except as otherwise expressly set forth herein, TBIL shall reimburse all Third Party Expenses and all FTE costs incurred by Takeda and its Affiliates to conduct any such transition activities after the end of such [***]-month period, unless the delay was caused primarily by the acts or omissions of Takeda or its Affiliates. Takeda shall not, during the period commencing on receipt of written notice of termination (or agreement to terminate if termination is pursuant to Section 15.2) until the transition activities contemplated in this Section 15.8(a) are complete or any time thereafter, make any public statement that could reasonably be expected to have a material adverse impact on the Manufacture, Development or Commercialization of any Product in any Terminated Country, except for public statements made in compliance with Applicable Laws and/or in good faith that are consistent with Takeda's internal publicity policies and procedures.

(xiii) Expenses. Except to the extent expressly set forth in this Section 15.8(a), each Party shall be solely responsible for any internal expenses and Third Party Expenses incurred by it and its Affiliates in connection with the activities set forth in this Section 15.8(a). To the extent Takeda is required to reimburse TBIL for any TBIL Internal Costs or Third Party Expenses, Takeda shall only be required to reimburse TBIL for those

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expenses which are actually incurred by TBIL and/or its Affiliates and are reasonable and specifically allocated to such transfer activities.

(xiv) TBIL ACKNOWLEDGES AND AGREES THAT EXCEPT FOR ANY MATERIALS PROVIDED UNDER A SUPPLY AGREEMENT THAT ARE SUBJECT TO THE REPRESENTATIONS AND WARRANTIES THEREIN (WHICH, FOR CLARITY, SHALL INCLUDE REPRESENTATIONS REGARDING COMPLIANCE WITH LAWS), ANY AND ALL INVENTORY AND OTHER DOCUMENTS AND MATERIALS PROVIDED TO TBIL BY OR ON BEHALF OF TAKEDA OR ANY OF ITS AFFILIATES IN CONNECTION WITH THIS SECTION 15.8(a) MAY BE EXPERIMENTAL IN NATURE AND MAY HAVE UNKNOWN CHARACTERISTICS. TBIL SHALL USE PRUDENCE AND REASONABLE CARE IN THE USE, HANDLING, STORAGE, TRANSPORTATION, DISPOSITION, AND CONTAINMENT OF SUCH TRANSFERRED ITEMS. WITHOUT LIMITING THE FOREGOING, EXCEPT FOR ANY MATERIALS PROVIDED UNDER A SUPPLY AGREEMENT THAT ARE SUBJECT TO THE REPRESENTATIONS AND WARRANTIES THEREIN, ANY AND ALL TRANSFERRED ITEMS ARE MADE AVAILABLE ON AN "AS IS" BASIS, WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

(xv) Designees. Notwithstanding anything to the contrary in this Section 15.8, in the event that TBIL specifies a designee to be assigned or otherwise transferred the relevant assets in accordance with this Section 15.8(a) (each such designee, a "Designee") (which Designee will be specified as soon as reasonably practical, but in no event later than twenty-five (25) Business Days following the effective date of the termination of this Agreement), TBIL shall cause such Designee to comply, and shall remain responsible for such Designee's actions, omissions and compliance with all terms hereof applicable to such assignment or transfer. Any actions of such Designee with respect to the activities and assets transferred under this Section 15.8 will be deemed activities of TBIL.

(b) Termination for TBIL's Material Breach or Insolvency. In the event that Takeda has the right to terminate pursuant to Section 15.3 or Section 15.4, Takeda shall have the right to continue under the terms of this Agreement (and for clarity, not exercise its right to terminate pursuant to such Sections), subject to the following modifications of the terms hereof (provided that Takeda notifies TBIL of such decision in writing no later than ten (10) Business Days before the effective date of termination):

(i) All Committees, including the JSC, shall be dissolved and TBIL's powers and responsibilities within all Committees shall automatically be assumed by Takeda (provided that, for clarity, in no event shall Takeda have the right to require TBIL to assume any additional or accelerated obligations, including any operational or financial obligations);

(ii) Takeda's obligations to provide TBIL with the Development Plan and Commercialization Plan, and updates thereto, shall terminate;

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(iii) All licenses granted to TBIL under this Agreement shall terminate upon the effective date of such termination; and

(iv) Takeda's payment obligations to TBIL under Article VIII shall be reduced by [***].

(v) In the event that Takeda does not elect to modify the Agreement as described pursuant to this Section 15.8(b), then the effects of termination as described in Section 15.8(a) shall apply as if this Agreement had terminated for reasons described in Section 15.8(a), except that all Third Party Expenses incurred by or on behalf of each Party and/or its Affiliates in connection with any transfer activities under Section 15.8(a) and all expenses incurred by TBIL and its Affiliates in connection with any Ongoing Trials shall be solely borne by TBIL, and TBIL shall reimburse Takeda for such Third Party Expenses which are actually incurred by or on behalf of Takeda and/or its Affiliates and are reasonable and specifically allocated to such transfer activities.

(c) Confidential Information. Upon any termination (but not expiration) of this Agreement in its entirety, Takeda shall use reasonable efforts to promptly return to TBIL (or destroy, at Takeda's option, with confirmation in writing of such destruction provided to TBIL) all Confidential Information of TBIL and all materials, items and devices related thereto or derived therefrom and all copies thereof, except to the extent necessary to comply with Applicable Laws or any obligations with respect to conducting any Clinical Trials hereunder (provided that upon completion of such obligations, Takeda shall be obligated to comply with this Section 15.8(c) in its entirety), provided that Takeda shall not be required to return or destroy any computer records or files containing TBIL's Confidential Information that have been created by Takeda's automatic archiving and back-up procedures to the extent that Takeda personnel (other than IT personnel) do not have access to such records or files in the ordinary course of business. In the event that, following the exercise of reasonable efforts, Takeda has not returned (or destroyed) any of the foregoing (the "Retained Information"), Takeda shall remain subject to the terms of Article IX with respect to the Retained Information for the duration set forth in Article IX.

(d) Sublicenses and Licenses. Unless the Parties otherwise agree in writing, and subject to Section 15.8(a)(x), upon termination of this Agreement for any reason, all sublicenses and subcontracts to the extent related to any Products in the Terminated Countries and not transferred under Section 15.8(a)(iv), and all licenses and other rights to the Takeda Technology with respect to the Products in the Terminated Countries, granted by or on behalf of Takeda, its Affiliates, its licensees and Sublicensees shall terminate.

(e) Takeda Obligations. Except in the case of termination under Section 15.6, as otherwise expressly set forth in this Article XV or TBIL's written request otherwise, Takeda shall continue to perform all its obligations under this Agreement with respect to the Development and Commercialization of Products after providing (or receiving) written notice of termination (or agreement to terminate if termination is pursuant to Section 15.2) until the effective date of termination (including its obligation to be responsible for certain of the TBIL Internal Costs and TBIL's and its Affiliates' Third Party Expenses hereunder), subject to Section 15.8(a)(vi) with respect to any Ongoing Trials, provided that [***], including any activities

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which are planned to be initiated during the applicable notice period [***]. In the event that this Agreement is terminated by Takeda pursuant to Section 15.6, the Parties shall immediately begin winding down all activities hereunder at Takeda's direction and Takeda shall be solely responsible for Third Party Expenses incurred by or on behalf of the Parties and its Affiliates in winding down the activities hereunder. Takeda shall have no obligation to make any Development, Regulatory Approval, or First Commercial Sale Milestone Payments following notice of termination to TBIL.

(f) Accrued Rights. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

(g) Survival. Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: Articles 9, 14, 15, 16, and 17 and Sections 1.1, 8.11, 8.12, 8.14, 12.1, and 12.2. Except as set forth in this Article XV or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

ARTICLE XVI
DISPUTE RESOLUTION

16.1 Disputes.

(a) Officers. Any dispute, controversy, claim, action or suit arising out of, relating to or in connection with this Agreement, including the breach, termination or validity thereof (each, a "Dispute"), shall first be submitted to the Officers for amicable resolution by consensus. If, for any reason, the Officers are unable to resolve, in writing and by consensus, the matter so referred to them within [***] days of such matter being first referred them, the Dispute shall either: (i) be referred to the License Arbitrator as provided in Section 16.1(c); or, (ii) in all other events, be finally resolved as provided in Section 16.1(b); provided that, a Party shall not be required to submit for amicable resolution under this Section 16.1(a) any application it may bring in a court of competent jurisdiction, or to an arbitral tribunal, for preliminary and temporary injunctive relief, or for pre-arbitral attachment or other order in aid of arbitration, as the case may be. For the avoidance of doubt, nothing in this Section 16.1(a) is intended to, or shall, restrict the scope and extent of Takeda's final decision-making authority as provided in Section 2.6(c), and any matter for which Takeda has final decision-making authority under Section 2.6(c) will not be subject to dispute resolution under this Article XVI .

(b) Jurisdiction. Except for Disputes submitted to the License Arbitrator as provided in Section 16.1(c) below, any Dispute that is not amicably resolved in writing as provided in Section 16.1(a) shall be resolved by the Federal Courts of the United States or the Courts of the State of New York, in each case located in the Borough of Manhattan, New York City, New York ("New York Courts"). In any such Dispute, each of the Parties irrevocably and unconditionally: (i) submits to the jurisdiction and venue of the New York Courts; (ii) waives, to the fullest extent it may do so, any objection, including any objection to the laying of venue or

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based on the grounds of forum non conveniens or any right of objection to jurisdiction on account of its place of incorporation or domicile, which it may now or hereafter have to the bringing of any such action or proceeding in any New York Court; and (iii) consents to service of process in the manner provided for notices in Section 17.9 below, or in any manner permitted by Applicable Law. EACH PARTY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, SUIT OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT; EACH PARTY CERTIFIES THAT IT HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS SET FORTH ABOVE IN THIS SECTION 16.1.

(c) License Arbitration.

(i) If, having undergone discussions as provided in Sections 15.8(a)(iv) and 16.1(a) above, the Parties cannot reach an agreement on the reasonable terms and conditions for the license contemplated in Section 15.8(a)(iv) above (the "License Terms"), then the Parties consent to submit the question of the License Terms to final and binding arbitration as provided in this Section 16.1(c). The seat of arbitration shall be New York, New York. The arbitration shall be conducted *ad hoc* by a sole arbitrator, who shall be an individual jointly appointed by the Parties (the "License Arbitrator"). If, for any reason, the Parties cannot jointly appoint the License Arbitrator within [***] days of the date of a written request by any Party for such joint appointment, then the License Arbitrator shall be appointed by the AAA in accordance with its list and strike procedure. When appointed by the AAA, the License Arbitrator must be a practicing or retired attorney with no less than [***] years of professional experience in the pharmaceutical industry.

(ii) Within [***] days following the date of appointment of the License Arbitrator, each of Takeda and TBIL shall submit to the License Arbitrator and to the other Party, simultaneously, a written report explaining in reasonable detail the terms of the license agreement that remain in dispute between the Parties, and the respective Party's position on those terms (each a "First Submission"). Within [***] days following the date of such submission to the License Arbitrator, each of Takeda and TBIL shall simultaneously submit to the License Arbitrator and to each other (a) a written response to the other Party's First Submission (each a "Second Submission"); and (b) proposed License Terms consistent with the requirements of Section 15.8(a)(iv) above ("Takeda Proposed Terms" and "TBIL Proposed Terms," respectively). If either or both of Takeda or TBIL fail to timely deliver their respective First Submission or Second Submission, then it or they shall be deemed to have waived their right to make that submission. The License Arbitrator may, in his or her sole discretion, order the Parties to attend a one-day hearing, in person or through counsel, to present oral arguments on their respective positions, if the License Arbitrator considers that such an oral hearing is advisable. The Parties consent and agree that nothing herein, or under Applicable Law, requires that the License Arbitrator hold such an oral hearing and that the License Arbitrator may make his or her final determination on the written materials presented to him or her.

(iii) Taking into account the requirements for a license in Section 15.8(a)(iv), the First Submissions, the Second Submissions, customary and ordinary industry

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practices and standards, and, where applicable, the record of a one-day hearing if one is held, the License Arbitrator shall issue an award designating either of (A) the Takeda Proposed Terms or (B) the TBIL Proposed Terms, as the License Terms provided in Section 15.8(a)(iv) above. The License Arbitrator shall not be permitted to, and may not, vary from or designate as the License Terms any terms that deviate from one or the other of the Takeda Proposed Terms or the TBIL Proposed Terms as submitted to him or her. If either of Takeda or TBIL has not timely submitted the Takeda Proposed Terms or TBIL Proposed Terms as provided in Section 16.1(c)(ii) above, then the License Arbitrator shall issue an award designating whichever of the Takeda Proposed Terms or TBIL Proposed Terms has been submitted to him or her as the License Terms. Except for certain other limited relief provided in Section 16.1(d) below, which permits the License Arbitrator to award certain relief to ensure the arbitration's confidentiality, award costs and fees for the arbitration, or issue preliminary or injunctive relief in aid of arbitration, the License Arbitrator shall only determine, and is only permitted to determine, which of the Takeda Proposed Terms or TBIL Proposed Terms should constitute the License Terms and may not, and in no event shall, award any other form of legal or equitable relief.

(iv) The award of the License Arbitrator will be final and binding on the Parties. Judgment upon the award may be entered by any court of competent jurisdiction. For the avoidance of doubt, the License Arbitrator shall act as an arbitrator, and not an expert, and his or her award, and this agreement to submit the question of the License Terms to the determination of the License Arbitrator, shall be governed by and construed in accordance with the Federal Arbitration Act, 9 U.S.C. § 1 et seq. (including Chapters 2 and 3 thereto) and, as and if applicable, Article 75 of the New York Civil Practice Law and Rules.

(d) General Terms for Arbitration. The terms of subsections (i), (ii) and (iii) below shall apply to any arbitration before a License Arbitrator under Section 16.1(c).

(i) The arbitration proceedings shall be confidential and the License Arbitrator, as the case may be, shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party shall make (or instruct the License Arbitrator, as the case may be, to make) any public announcement with respect to the proceedings or decision of the License Arbitrator without prior written consent of the other Party. The existence of a dispute submitted to arbitration, and the outcome, shall be kept in confidence by the License Arbitrator and the Parties, their Affiliates, their counsel, insurers and re-insurers, accountants and auditors, and any Person necessary to the conduct of the proceeding; provided that, the confidentiality obligations imposed in this Section 16.1(d)(i) shall not apply (1) if disclosure is required by Applicable Law; (2) to the extent necessary to enforce the rights arising out of the award; or (3) to the extent necessary to otherwise protect or pursue a legal right.

(ii) In any arbitration proceeding, the License Arbitrator may also, in its discretion, award the expenses and fees of the proceedings, including reasonable attorneys' expenses and fees, to the prevailing Party.

(iii) By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other

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order in aid of arbitration proceedings. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the License Arbitrator shall have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the License Arbitrator orders to that effect.

ARTICLE XVII
MISCELLANEOUS

17.1 Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available at law or in equity.

17.2 Amendments. No provision in this Agreement shall be supplemented, deleted, or amended except in a writing executed by an authorized representative of each of TBIL and Takeda.

17.3 Interpretation. The headings and captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the words "either" and "or" are not exclusive and "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if"; (c) references to a Person are also to its permitted successors and assigns; (d) references to the singular shall include the plural and vice versa; (e) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; (f) references to an "Article," "Section," "Exhibit" or "Schedule" refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement; (g) references to "$", "Dollar" or otherwise to dollar amounts refer to the lawful currency of the United States; (h) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement; (i) references to days (other than Business Days) means calendar days; and (j) the words "hereof," "hereto," "herein" or "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement.

17.4 Affiliates. Each Party may perform its obligations hereunder through one or more of its Affiliates. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. To the extent that this Agreement expressly obligates any Affiliates of either Party (including, for clarity, as set forth in the license grants set forth in Article III) such Party shall cause its applicable Affiliates to comply with such obligations as if it were a party hereto, and such Party shall remain responsible for the actions and/or omissions of such Affiliates in connection with this Agreement.

17.5 Relationship of the Parties. For all purposes and notwithstanding any other provision of this Agreement to the contrary, the Parties' respective legal relationship under this

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Agreement to each other shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

17.6 Force Majeure. Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, acts of God (including fire, floods, tsunami and earthquakes) or other factors outside the reasonable control of the affected Party ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

17.7 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, including any federal law as it would be applied in the State of New York, without regarding to the conflict of laws principals thereof that would mandate the application of the laws of any other jurisdiction.

17.8 Assignment. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either TBIL or Takeda without (a) the prior written consent of TBIL in the case of any assignment by Takeda or (b) the prior written consent of Takeda in the case of an assignment by TBIL, except in each case (i) to an Affiliate of the assigning Party, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any Third Party who acquires all or substantially all of the business of the assigning Party to which this Agreement relates, by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. Any attempted assignment in violation of this Section 17.8 shall be void. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

17.9 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

If to TBIL:

Theravance Biopharma Ireland Limited
Fitzwilliam Hall, Fitzwilliam Place
Dublin 2
Ireland
Facsimile: [***]

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Attn: President

with a copy to:

Theravance Biopharma US, Inc.
901 Gateway Boulevard
South San Francisco, CA 94080
Facsimile: [***]
Attn: Head, Business Development

and a copy to:

Theravance Biopharma, Inc.
c/o Theravance Biopharma US, Inc.
901 Gateway Boulevard
South San Francisco, CA 94080
Facsimile: [***]
Attn: General Counsel

If to Takeda:

Millennium Pharmaceuticals, Inc.
40 Landsdowne Street
Cambridge, MA 02139
Facsimile: [***]
Attn: [***]

with a copy to:

Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015
Facsimile: [***]
Attn: General Counsel

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

17.10 Severability. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions which most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities.

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17.11 Limitation of Damages. EXCEPT WITH RESPECT TO BREACH OF ARTICLE IX OR THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES.

17.12 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

17.13 Entire Agreement. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties, whether written or oral. As of the date hereof, (a) the Confidentiality Agreement is hereby terminated without further force and effect, superseded by the terms of this Agreement (including Article IX) and, (b) for clarity, all obligations between the Parties relating to confidentiality, including with respect to confidential information exchanged between the Parties under the Confidentiality Agreement, shall be governed by the terms of this Agreement (including Article IX).

17.14 Third Party Beneficiaries. This Agreement is for the sole benefit of the Parties and their permitted successors and assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.

17.15 Counterparts. This Agreement may be executed in two or more counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

17.16 No Strict Construction. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

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

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IN WITNESS WHEREOF, TBIL and Takeda have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

THERAVANCE BIOPHARMA IRELAND LIMITED

By /s/ Ann Brady
Name: Dr. Ann Brady
Title: President, Theravance Biopharma Ireland Limited

MILLENNIUM PHARMACEUTICALS, INC.

By /s/ Christophe Bianchi
Name: Christophe Bianchi
Title: President

[Signature Page]

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Schedule 9.5

Press Release

Takeda Licenses Global Rights to Theravance Biopharma's TD-8954, a Novel 5-HT4 Agonist and Motility Agent for Gastrointestinal Motility Disorders

Deal Provides Takeda Global Rights to Selective 5-HT4 Agonist; Highlights Takeda's Commitment to Gastroenterology as a Core Therapeutic Area

Osaka, Japan, June xx, 2016, and Dublin, Ireland; June xx, 2016 — Takeda Pharmaceutical Company Limited (TSE: 4502) ("Takeda") and Theravance Biopharma, Inc. (NASDAQ: TBPH) ("Theravance Biopharma") today announced that the companies have entered into a global license, development and commercialization agreement for TD-8954, a selective 5-HT4 receptor agonist being investigated for potential use in the treatment of gastrointestinal motility disorders, including enteral feeding intolerance ("EFI").

TD-8954 is being developed for the short-term use with EFI to achieve early nutritional adequacy in critically ill patients at high nutritional risk, an indication for which the compound received U.S. Food and Drug Administration (FDA) Fast Track Designation. Theravance Biopharma has most recently completed a study evaluating the safety, tolerability and pharmacodynamics of a single dose of the compound administered intravenously compared to metoclopramide in critically ill patients with EFI.

"The addition of TD-8954 to our portfolio highlights Takeda's commitment to the development of treatments to improve the health of patients with gastroenterological disorders," said Asit Parikh, M.D., Ph.D., Head, Gastroenterology Therapeutic Area Unit, Takeda. "As a leader in gastroenterology, Takeda has a history of bringing innovative treatments to patients where there is significant unmet need. We believe that TD-8954 has the potential to deliver therapeutic benefit to patients with gastrointestinal motility disorders, including EFI. Today EFI impacts approximately one million Americans and there are currently no FDA-approved treatment options available."

"This is an important licensing deal for Theravance Biopharma as it provides a path forward for the development of this much-needed treatment option. Our single-dose study of TD-8954 in critically ill patients with EFI provided early confidence in the potential for TD-8954 to improve gastric emptying time. This is important as delayed gastric emptying makes it more difficult to feed patients in the ICU, slowing their recovery time, extending their stay in the ICU and increasing the risk of ICU-related complications," said Rick E Winningham, Chairman and Chief Executive Officer of Theravance Biopharma. "Takeda is an industry leader in the development of treatments for gastrointestinal disorders, which we believe makes the company an ideal partner to drive the continued advancement of TD-8954."

Theravance Biopharma will receive an upfront cash payment of $15 million and will be eligible to receive success based development and sales milestone payments as well as double digit royalties

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on worldwide net sales by Takeda. The first $110 million of potential milestones are associated with the development, regulatory and commercial launch milestones for EFI or other intravenously dosed indications. The transaction is expected to close during the second calendar quarter of 2016, and is subject to customary closing conditions and clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act").

About Takeda

Takeda Pharmaceutical Company Limited (TSE: 4502) is a global, R&D-driven pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its research efforts on oncology, gastroenterology and central nervous system therapeutic areas. It also has specific development programs in specialty cardiovascular diseases as well as late-stage candidates for vaccines. Takeda conducts R&D both internally and with partners to stay at the leading edge of innovation. New innovative products, especially in oncology, central nervous system and gastroenterology, as well as its presence in emerging markets, fuel the growth of Takeda. More than 30,000 Takeda employees are committed to improving quality of life for patients, working with our partners in health care in more than 70 countries. For more information, visit http://www.takeda.com/news.

Takeda's Commitment to Gastroenterology

Takeda is a global leader in gastroenterology. With expertise spanning more than 25 years, the company's dedication to innovation continues to evolve and have a lasting impact. ENTYVIO® (vedolizumab) demonstrates Takeda's global capabilities and expansion into the specialty care market in gastroenterology and biologics. Designed and developed specifically to target the gastrointestinal (GI) tract, ENTYVIO was launched in 2014 for the treatment of adults with moderate to severe ulcerative colitis and Crohn's disease. TAKECAB® (vonoprazan fumarate) is Takeda's potassium-competitive acid blocker and was launched in Japan in 2015. Takeda also markets motility agent AMITIZA® (lubiprostone), which originally launched in 2006 for the treatment of chronic idiopathic constipation, and received subsequent approval to treat irritable bowel syndrome with constipation and opioid-induced constipation. Preceding these notable launches, Takeda pioneered gastroenterological breakthroughs in proton pump inhibitors beginning in the 1990's with lansoprazole. Through specialized and strategic in-house development, external partnerships, in-licensing and acquisitions, Takeda currently has a number of promising early stage GI assets in development, and remains committed to delivering innovative, therapeutic options for patients with gastrointestinal and liver diseases.

About Theravance Biopharma

Theravance Biopharma is a diversified biopharmaceutical company with the core purpose of creating medicines that make a difference in the lives of patients suffering from serious illness. Our pipeline of internally discovered product candidates includes potential best-in-class medicines to address the unmet needs of patients being treated for serious conditions primarily in the acute care setting. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the U.S., Europe and certain other countries for certain difficult-to-treat infections. Revefenacin (TD-4208) is a long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Our neprilysin (NEP) inhibitor program is designed to develop selective NEP inhibitors for the treatment of a range of major cardiovascular and renal diseases, including acute and chronic heart failure, hypertension and chronic kidney diseases such as diabetic nephropathy. Our research efforts

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are focused in the areas of inflammation and immunology, with the goal of designing medicines that provide targeted drug delivery to tissues in the lung and gastrointestinal tract in order to maximize patient benefit and minimize risk. The first program to emerge from this research is designed to develop GI-targeted pan-Janus kinase (JAK) inhibitors for the treatment of a range of inflammatory intestinal diseases.

In addition, we have an economic interest in future payments that may be made by Glaxo Group Limited or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain drug development programs, including the Closed Triple (the combination of fluticasone furoate, umeclidinium, and vilanterol), currently in development for the treatment of COPD and asthma.

For more information, please visit www.theravance.com.

Takeda's Forward-Looking Statements

This press release contains "forward-looking statements." Forward-looking statements include all statements other than statements of historical fact, including plans, strategies and expectations for the future, statements regarding the expected timing of filings and approvals relating to the transaction, the expected timing of the completion of the transaction, the ability to complete the transaction or to satisfy the various closing conditions, future revenues and profitability from or growth or any assumptions underlying any of the foregoing. Statements made in the future tense, and words such as "anticipate," "expect," "project," "continue," "believe," "plan," "estimate," "pro forma," "intend," "potential," "target," "forecast," "guidance," "outlook," "seek," "assume," "will," "may," "should," and similar expressions are intended to qualify as forward-looking statements. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors and security holders are cautioned not to place undue reliance on these forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to: required regulatory approvals for the transaction may not be obtained in a timely manner, if at all; the conditions to closing of the transaction may not be satisfied; competitive pressures and developments; applicable laws and regulations; the success or failure of product development programs; actions of regulatory authorities and the timing thereof; changes in exchange rates; and claims or concerns regarding the safety or efficacy of marketed products or product candidates in development.

The forward-looking statements contained in this press release speak only as of the date of this press release, and neither Theravance Biopharma nor Takeda undertakes any obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If one or more of these statements is updated or corrected, investors and others should not conclude that additional updates or corrections will be made.

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Theravance Biopharma's Forward-Looking Statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Theravance Biopharma intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Examples of such statements include statements relating to: the Company's strategies, plans and objectives, the Company's regulatory strategies and timing and results of clinical studies, the potential benefits and mechanisms of action of the Company's product and product candidates and the Company's expectations for product candidates through development and commercialization. These statements are based on the current estimates and assumptions of the management of Theravance Biopharma as of the date of the press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Theravance Biopharma to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate the Company's product candidates are unsafe or ineffective, the feasibility of undertaking future clinical trials for our product candidates based on FDA policies and feedback, dependence on third parties to conduct clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates. Other risks affecting Theravance Biopharma are described under the heading "Risk Factors" contained in Theravance Biopharma's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 10, 2016. In addition to the risks described above and in Theravance Biopharma's other filings with the SEC, other unknown or unpredictable factors also could affect Theravance Biopharma's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Theravance Biopharma assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law.

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CONTACTS:

For Theravance Biopharma:
Renee Gala
Chief Financial Officer
650-808-4045
investor.relations@theravance.com

Tim Brons
Vida Strategic Partners (media)
646-319-8981
tbrons@vidasp.com

For Takeda:
Tsuyoshi Tada
Media in Japan
tsuyoshi.tada@takeda.com
+81 33 278 2417

Elissa Johnsen
Media outside of Japan
elissa.johnsen@takeda.com
+1 224 554 3185

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Schedule 10.2

None.

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Schedule 10.5(d)(vii)

None.

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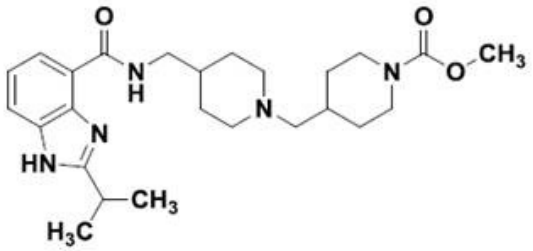
Exhibit 1.1(a)

Chemical Structure of the Compound



TD-8954

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Exhibit 1.1(b)

TBIL Patents

(As of the Execution Date and to be updated by TBIL prior to the Effective Date)

Patent Family [***]

Title: [***]

Country	Application No	Filing Date	Patent No.	Issue Date

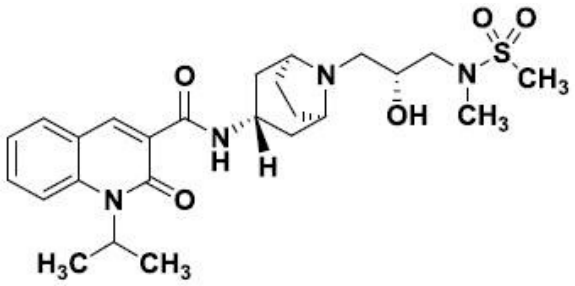
[***]

[End of Exhibit 1.1(b)]

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Exhibit 1.1(c)

Chemical Structure of Velusetrag



Velusetrag

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Exhibit 8.5

Example of Royalty Adjustments and Royalty Floor

Third Party IP. By way of example only, if: (i) Takeda deems that it is necessary (in accordance with Section 8.4(a)) to obtain a license to Third Party IP with respect to a given country; (ii) the amount of royalties due to the Third Party under such license with respect to a particular Calendar Quarter is [***]; and (iii) the royalties payable by Takeda to TBIL under Section 8.3 during the applicable Calendar Quarter based upon the Net Sales in such country are [***] prior to any adjustments, the amount due to TBIL following the adjustment provided for in Section 8.4(a) and the application of the royalty floor provided for in Section 8.5 would be calculated as follows:

Total royalty amount prior to adjustment:	$[***]
Reduction in royalty amount due to Third Party license (Section 8.4(a)):	[(.50)($[***])] = $[***]
Maximum royalty reduction under Section 8.4(a):	[(.50)($[***)]] = $[***]
Royalty floor under Section 8.5:	[(.50)($[***])] = $[***]
Royalty amount payable to TBIL following Section 8.4(a) adjustment and application of maximum royalty reduction under Section 8.4(a):	**$[***]**
Reduction under Section 8.4(a) carried forward to subsequent Calendar Quarter:	$[***] – $[***] = (**$[***]**)

Generic Competition In A Country. By way of example only, if: (i) the Product Share with respect to a Product in a country in a Calendar Quarter is [***] and (ii) the royalties payable by Takeda to TBIL pursuant to Section 8.3 during the applicable Calendar Quarter for the Product based upon the Net Sales in such country are [***] prior to any adjustments, and (iii) the amount due by Takeda for a license to Third Party IP pursuant to Section 8.4(a) with respect to such Product in such country is [***], then the amount due to TBIL following the adjustments provided for in both Section 8.3(c) and Section 8.4(a) and the application of the royalty floor provided for in Section 8.5 would be calculated as follows:

Total royalty amount prior to adjustment:	$[***]
Royalty amount due as a result of Generic Competition in such Country (Section 8.3(c)):	$[***] – [(.25)($[***])] = $[***]
Reduction in royalty amount due to Third Party IP license (Section 8.4(a)):	$[***] – [(.50)($[***])] = $[***]
Royalty floor under Section 8.5:	(.50)($[***]) = $[***]

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Royalty amount payable to TBIL following Section 8.3(c) and Section 8.4(a) adjustments and application of royalty floor under Section 8.5:	**$[***]**

Generic Competition In A Country. By way of example only, if (i) the Product Share with respect to a Product in a country in a Calendar Quarter is [***]; (ii) the royalties payable by Takeda to TBIL pursuant to Section 8.3 during the applicable Calendar Quarter for the Product based upon the Net Sales in such country are [***] prior to any adjustments, and (iii) the amount due for a license to Third Party IP pursuant to Section 8.4(a) with respect to such Product in such country is [***], then the amount due to TBIL following the adjustment provided for in Section 8.3(c) and Section 8.4(a) and the application of the royalty floor provided for in Sections 8.4(a) and Section 8.5 would be calculated as follows:

Total royalty amount prior to adjustment:	$[***]
Royalty amount due as a result of Generic Competition in A Country (Section 8.3(c)):	$[***] - [(.50)($[***])] = $[***]
Reduction in royalty amount due to Third Party IP license (Section 8.4(a)):	(.50)($[***]) = $[***] {Note: Without application of royalty floor maximum reduction under Section 8.4(a) in example Calendar Quarter is capped at $[***]}
Total royalty amount due prior to application of maximum reduction under Section 8.4(a) or royalty floor	$[***] – $[***] = $[***]
Royalty floor(Section 8.5)	(.50)($[***]) = $[***]
Royalty amount payable to TBIL following Section 8.3(c) and Section 8.4(a) adjustments and application of maximum reduction under Section 8.4(a) and royalty floor under Section 8.5:	**$[***]**
Reduction under Section 8.4(a)carried forward to subsequent Calendar Quarter:	$[***] – $[***] = **($[***])**

***CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

Exhibit 10.2

AMENDMENT NO. 1 TO THE LICENSE, DEVELOPMENT, AND COMMERCIALIZATION AGREEMENT

THIS AMENDMENT NO. 1 ("Amendment No. 1") is entered into this 4th day of August, 2016 ("Amendment Effective Date") and amends the Commercialization Agreement dated March 8, 2013, the current parties to which are Clinigen Group PLC, ("Clinigen"), and Theravance Biopharma Ireland Limited (referred to as "Theravance"). (the "Agreement"). Unless otherwise specifically stated herein, capitalized terms used herein and not defined shall have the same meaning set forth in the Agreement. References to "Sections" and "Exhibits" herein shall mean the corresponding sections and exhibits set forth in the Agreement.

WHEREAS, Theravance and Clinigen have mutually agreed to terminate the Agreement; and

WHEREAS, the Parties have agreed to work together in transition of the Licensed Product, Marketing Authorization(s) and related matters in contemplation of such termination, in accordance with the Agreement as amended herein.

NOW THEREFORE, the Parties agree as follows:

1. Section 4.01(a) is hereby amended by revising the last sentence of Section 4.01(a) as follows:

   Promptly after the Amendment Effective Date, Clinigen will use Diligent Efforts to transfer the relevant Marketing Authorization(s) to Theravance or Theravance's designee in the Territory as soon as reasonably practicable and upon such transfer, Theravance or Theravance's designee will become the Marketing Authorization(s) holder for such Marketing Authorization(s). Theravance on behalf of itself and any designee hereby agrees to accept such transfer of the Marketing Authorization(s). The parties agree to work together in good faith to achieve this aim. For the purpose of clarity and other than as set forth in Section 4.01(c), this transfer of the relevant Marketing Authorization(s) from Clinigen to Theravance will not require any payment from Theravance to Clinigen nor from Clinigen to Theravance.

2. Section 4.01(c) will be amended as follows:

   Funding Responsibility. As of the Amendment Effective Date, Theravance shall bear all costs and expenses associated with maintaining and obtaining any further Marketing Authorization(s) Approvals for the Licensed Product in each Country of the Territory and after such date Clinigen shall have no obligation with respect to such costs and expenses.

3. The parties acknowledge and agree that Section 14.05(b) of the Agreement will govern the mutual termination of the Agreement effected by this Amendment No. 1. Clinigen understands that Theravance hereby elects to have all provisions of Section 14.05(b) apply to the termination for purposes of determining the

respective rights, obligations and responsibilities of the parties after the Amendment Effective Date, and both parties agree to be bound thereby.

4. Notwithstanding the termination of the Agreement hereby, Clinigen agrees to continue to perform the following activities on Theravance's behalf until such activities can be transitioned to Theravance or Theravance's designee. On or before the Amendment Effective Date, Clinigen will provide Theravance with a written list of all current agreements and obligations related to its rights and responsibilities under the Agreement. Theravance will be responsible for Clinigen's reasonable out of pocket costs and expenses associated with performing these activities, subject to Theravance's receipt of reasonably detailed invoices from Clinigen:

(i) Perform those activities that are the responsibility of Clinigen with respect to exchange of drug safety information as set forth in Section 8.03 of the Agreement and in the Safety Data Exchange Agreement between the Parties dated October 1, 2013 (the "SDEA").

(ii) Respond to medical information inquiries with respect to Licensed Product that may be received by Clinigen's Medical Information Department;

(iii) Maintain sole responsibility for all Regulatory Filings as set forth in Section 8.01 of the Agreement;

(iv) Continue to support Theravance with required or relevant on-going interactions with Government Authorities (including but not limited to the Medicines & Healthcare Products Regulatory Agency or the European Medicines Agency) during the time period between the Amendment Effective Date and the transfer of the Marketing Authorization(s) to Theravance); and

(v) Sell Licensed Product in the Territory solely in response to unsolicited purchase requests by prescribers who have demonstrated a critical medical need for a specific patient(s) ("Medically Necessary Supply Program"), until such time as Theravance or Theravance's designee becomes the Market Authorization(s) holder.

For clarity, except with respect to Licensed Product supply under the Medically Necessary Supply Program, Commercialization, marketing and sale of Licensed Product by Clinigen shall cease as of the Amendment Effective Date

The terms and conditions of the Agreement shall apply to Clinigen's conduct of the activities described in this Paragraph 4 as though the Agreement were in full force and effect.

5. Theravance shall not encourage the sale of, or attempt to sell, Licensed Product under any Clinigen discount or rebate agreement that may be in effect on or after the Amendment Effective Date.

6. With respect to Licensed Product transferred to Theravance hereunder that bears Clinigen labeling and Clinigen registration numbers ("Clinigen-Labeled Licensed Product"), Clinigen shall be liable for governmental rebate and chargeback claims associated with Clinigen-Labeled Licensed Product that are received on or before the effective date of transfer of the relevant Marketing Authorization(s). Thereafter, Theravance shall be liable for all governmental rebate and chargeback claims associated with Clinigen-Labeled Licensed Product. Clinigen shall promptly forward to Theravance any invoices for such Clinigen-Labeled Licensed Product rebate and chargeback claims that are Theravance's financial responsibility.

7. The Parties shall mutually agree on any public account of the termination of the Agreement. Theravance and Clinigen will refrain from any other external communications related to the termination of the Agreement, this Amendment No. 1 and the transition of the Licensed Product from Clinigen back to Theravance without the prior approval of both Parties, which approval will not be unreasonably withheld or conditioned. Clinigen acknowledges that Theravance or its affiliates may be required by law to file a copy of this Amendment No. 1 with the U.S. Securities and Exchange Commission and hereby consents to that filing, if required.

8 Theravance and Clinigen entered into a Supply Agreement dated April 4, 2014, as amended ("the Supply Agreement") in conjunction with the Commercialization Agreement. The Parties acknowledge and agree that pursuant to Section 6.1 of the Supply Agreement, the Supply Agreement shall terminate simultaneously with termination of the Commercialization Agreement.

9. The Parties acknowledge and agree that pursuant to Section 11.2 of the SDEA, the SDEA shall also terminate simultaneously with termination of the Commercialization Agreement other than as set forth in Section 11.3 of the SDEA.

10. The Parties acknowledge and agree that there are no Clinigen Patents or Clinigen Inventions as contemplated under the Agreement.

11. By this Amendment No. 1 and effective as of the Amendment Effective Date, the parties have terminated the Agreement subject to (i) the amendments contained herein (which are intended to clarify certain rights and obligations of the parties after this termination) and (ii) Section 14.06 of the Agreement (which governs other accrued rights and surviving obligations of the parties after this termination).

[*SIGNATURES ON THE FOLLOWING PAGE]*

IN WITNESS WHEREOF, Theravance and Clinigen have executed this Amendment No. 1 by their duly authorized representatives as of the Amendment Effective Date.

THERAVANCE BIOPHARMA IRELAND LIMITED		**CLINIGEN GROUP, PLC**	
By:	/s/ Ann Brady	By:	/s/ Peter George
Name:	Ann Brady	Name:	Peter George
Title:	President, TBIL	Title:	CEO

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Rick E Winningham, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance Biopharma, 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; and

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

/s/ Rick E Winningham
Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Renee D. Gala, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance Biopharma, 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; and

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2016

/s/ Renee D. Gala
Renee D. Gala
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and six months ended June 30, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the period covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the period covered by such Quarterly Report on Form 10-Q.

Date: August 8, 2016

By: /s/ Rick E Winningham
Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Renee D. Gala, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Biopharma, Inc. on Form 10-Q for the three and six months ended June 30, 2016 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. at the end of the period covered by such Quarterly Report on Form 10-Q and results of operations of Theravance Biopharma, Inc. for the period covered by such Quarterly Report on Form 10-Q.

Date: August 8, 2016

By: /s/ Renee D. Gala
Renee D. Gala
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)