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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**Form 10-Q**

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(Mark One)

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

For the quarterly period ended March 31, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-36033

**THE RAVANCE 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

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of May 1, 2018, the number of the registrant's outstanding ordinary shares was 54,853,858.

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**PART I. FINANCIAL INFORMATION**  
**ITEM 1. FINANCIAL STATEMENTS**

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

|  | March 31,<br>2018 | December 31,<br>2017 |
|--|-------------------|----------------------|
| <b>Assets</b>  |                   |                      |
| Current assets:  |                   |                      |
| Cash and cash equivalents  | \$ 125,831        | \$ 88,980            |
| Short-term marketable securities   | 292,700           | 259,586              |
| Accounts receivable, net of allowances of \$888 and \$992 at March 31, 2018 and December 31, 2017, respectively  | 1,973             | 2,253                |
| Receivables from collaborative arrangements  | 2,845             | 7,109                |
| Prepaid taxes  | 926               | 291                  |
| Other prepaid and current assets   | 5,326             | 3,700                |
| Inventories  | 17,217            | 16,830               |
| Total current assets   | 446,818           | 378,749              |
| Property and equipment, net  | 10,329            | 10,157               |
| Long-term marketable securities  | 16,999            | 41,587               |
| Tax receivable   | 3,324             | 8,191                |
| Restricted cash  | 833               | 833                  |
| Other assets   | 1,805             | 1,883                |
| Total assets   | \$ 480,108        | \$ 441,400           |
| <b>Liabilities and Shareholders' Equity</b>  |                   |                      |
| Current liabilities:   |                   |                      |
| Accounts payable   | \$ 5,085          | \$ 5,924             |
| Accrued personnel-related expenses   | 21,989            | 24,136               |
| Accrued clinical and development expenses  | 16,435            | 20,657               |
| Other accrued liabilities  | 11,508            | 11,710               |
| Deferred revenue   | 50,162            | 125                  |
| Total current liabilities  | 105,179           | 62,552               |
| Convertible senior notes, net  | 224,014           | 223,746              |
| Deferred rent  | 5,772             | 3,668                |
| Long-term deferred revenue   | 45,651            | 1,436                |
| Other long-term liabilities  | 36,085            | 34,820               |
| Commitments and contingencies  |                   |                      |
| <b>Shareholders' equity</b>  |                   |                      |
| Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding  | —                 | —                    |
| Ordinary shares, \$0.00001 par value: 200,000 shares authorized; 54,798 and 54,381 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively | 1                 | 1                    |
| Additional paid-in capital   | 925,968           | 913,650              |
| Accumulated other comprehensive loss   | (854)             | (733)                |
| Accumulated deficit  | (861,708)         | (797,740)            |
| Total shareholders' equity   | 63,407            | 115,178              |
| Total liabilities and shareholders' equity   | \$ 480,108        | \$ 441,400           |

*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<br>March 31, |             |
|---|---------------------------------|-------------|
|   | 2018                            | 2017        |
| <b>Revenue:</b>   |                                 |             |
| Product sales   | \$ 3,679                        | \$ 3,050    |
| Revenue from collaborative arrangements                     | 4,640                           | 37          |
| Total revenue   | 8,319                           | 3,087       |
| <b>Costs and expenses:</b>                                  |                                 |             |
| Cost of goods sold  | 826                             | 565         |
| Research and development (1)                                | 47,765                          | 40,565      |
| Selling, general and administrative (1)                     | 24,704                          | 20,786      |
| Total costs and expenses                                    | 73,295                          | 61,916      |
| Loss from operations  | (64,976)                        | (58,829)    |
| Interest expense  | (2,137)                         | (2,137)     |
| Interest and other income, net                              | 2,170                           | 1,030       |
| Loss before income taxes                                    | (64,943)                        | (59,936)    |
| Provision for income taxes                                  | 144                             | 5,383       |
| Net loss  | \$ (65,087)                     | \$ (65,319) |
| <b>Net loss per share:</b>                                  |                                 |             |
| Basic and diluted net loss per share                        | \$ (1.22)                       | \$ (1.27)   |
| Shares used to compute basic and diluted net loss per share | 53,256                          | 51,617      |
| Net unrealized loss on available-for-sale investments       | (120)                           | (19)        |
| Total comprehensive loss                                    | \$ (65,207)                     | \$ (65,338) |

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

| <b>(In thousands)</b>                  | Three Months Ended<br>March 31, |           |
|--|---------------------------------|-----------|
|  | 2018                            | 2017      |
| Research and development               | \$ 6,559                        | \$ 5,101  |
| Selling, general and administrative    | 7,439                           | 5,168     |
| Total share-based compensation expense | \$ 13,998                       | \$ 10,269 |

*See accompanying notes to condensed consolidated financial statements.*

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

|  | Three Months Ended<br>March 31, |                          |
|--|---------------------------------|--------------------------|
|  | 2018                            | 2017                     |
| <b>Operating activities</b>  |                                 |                          |
| Net loss   | \$ (65,087)                     | \$ (65,319)              |
| Adjustments to reconcile net loss to net cash used in operating activities:                                  |                                 |                          |
| Depreciation and amortization  | 900                             | 1,083                    |
| Share-based compensation   | 13,998                          | 10,269                   |
| Other  | (890)                           | 53                       |
| Changes in operating assets and liabilities:   |                                 |                          |
| Accounts receivable  | 280                             | (587)                    |
| Receivables from collaborative arrangements  | 4,264                           | 1,437                    |
| Other prepaid and current assets   | (1,578)                         | (1,237)                  |
| Inventories  | (371)                           | 140                      |
| Tax receivable   | 5,092                           | —                        |
| Other assets   | —                               | 266                      |
| Accounts payable   | (449)                           | 2,004                    |
| Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities | (5,076)                         | (3,214)                  |
| Deferred rent  | 2,104                           | (292)                    |
| Deferred revenue   | 95,371                          | 17                       |
| Other long-term liabilities  | 1,267                           | 5,354                    |
| Net cash provided by (used in) operating activities  | <u>49,825</u>                   | <u>(50,026)</u>          |
| <b>Investing activities</b>  |                                 |                          |
| Purchases of property and equipment  | (2,771)                         | (587)                    |
| Purchases of marketable securities   | (54,839)                        | (159,217)                |
| Maturities of marketable securities  | 46,299                          | 36,282                   |
| Proceeds from the sales of fixed assets  | 17                              | —                        |
| Net cash (used in) investing activities  | <u>(11,294)</u>                 | <u>(123,522)</u>         |
| <b>Financing activities</b>  |                                 |                          |
| Proceeds from option exercises   | 35                              | 2,816                    |
| Repurchase of shares to satisfy tax withholding  | (1,715)                         | (4,032)                  |
| Net cash (used in) financing activities  | <u>(1,680)</u>                  | <u>(1,216)</u>           |
| <b>Net increase (decrease) in cash, cash equivalents, and restricted cash</b>                                | <b>36,851</b>                   | <b>(174,764)</b>         |
| <b>Cash, cash equivalents, and restricted cash at beginning of period</b>                                    | <b>89,813</b>                   | <b>345,542</b>           |
| <b>Cash, cash equivalents, and restricted cash at end of period</b>  | <b><u>\$ 126,664</u></b>        | <b><u>\$ 170,778</u></b> |
| <b>Supplemental disclosure of cash flow information</b>  |                                 |                          |
| Cash received for income taxes, net  | \$ 4,473                        | \$ —                     |

*See accompanying notes to condensed consolidated financial statements.*

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

**1. Organization and Summary of Significant Accounting Policies**

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 help improve the lives of patients suffering from serious illness.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, intestinally restricted pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

***Basis of Presentation***

Our condensed consolidated financial information as of March 31, 2018, and the three months ended March 31, 2018 and 2017 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 US 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, 2017 financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission (“SEC”) on February 28, 2018.

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018 and recognized the cumulative effect of ASC 606 at the date of initial application. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. We recorded a reduction to the opening balance of accumulated deficit of approximately \$1.1 million and a corresponding reduction in deferred revenue as of January 1, 2018 due to ASC 606’s cumulative adoption impact on our collaborative arrangements. Our product sales revenue under ASC 606 would not have been materially different under the legacy Accounting Standards Codification, Topic 605, *Revenue Recognition* (“ASC 605”).

Effective January 1, 2018, we adopted Accounting Standards Update 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”) that changed the presentation of restricted cash and cash equivalents on the condensed consolidated statement of cash flows. Restricted cash are now included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the condensed consolidated statements of cash flows. To conform to the presentation under ASU 2016-18, we revised the amounts previously reported on the condensed consolidated statements of cash flows for the comparable prior year period.

### **Significant Accounting Policies**

Other than the policies below, 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, 2017.

#### **Revenue Recognition**

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

#### **Product Sales**

We sell VIBATIV in the US market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors. We recognize VIBATIV product sales and related cost of product sales when the distributors obtain control of the drug product, which is at the time title transfers to the distributors.

Product sales are recorded on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

**Sales Discounts:** We offer cash discounts to certain customers as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the expected discount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

**Chargebacks and Government Rebates:** For VIBATIV sales in the US, we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service ("PHS"), as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such healthcare providers and our expectation about future utilization rates. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payor mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced

directly to us are recorded in other accrued liabilities on the condensed consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

*Distribution Fees:* We have contracts with our distributors in the US that include terms for distribution-related fees. We determine distribution-related fees based on a percentage of the product sales price, and we record the distribution fees as an allowance against accounts receivable.

*Product Returns:* We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that has been sold to our distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We record our product return reserves as accrued other liabilities.

*Allowance for Doubtful Accounts:* We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2018, there was no allowance for doubtful accounts related to customer payments.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2018.

| <b>(In thousands)</b>                     | <b>Chargebacks,<br/>Discounts and<br/>Fees</b> | <b>Government<br/>and Other<br/>Rebates</b> | <b>Returns</b> | <b>Total</b>    |
|---|--|---|----------------|-----------------|
| Balance at December 31, 2017              | \$ 992   | \$ 352                                      | \$ 947         | \$ 2,291        |
| Provision related to current period sales | 1,482  | 174   | 79             | 1,735           |
| Adjustment related to prior period sales  | (71)   | 73  | (449)          | (447)           |
| Credit or payments made during the period | (1,515)  | (238)                                       | (49)           | (1,802)         |
| Balance at March 31, 2018                 | <u>\$ 888</u>                                  | <u>\$ 361</u>                               | <u>\$ 528</u>  | <u>\$ 1,777</u> |

#### *Collaborative Arrangements*

We enter into collaborative arrangements with partners that fall under the scope of both ASC 606 and Accounting Standards Codification, Topic 808, *Collaborative Arrangements* ("ASC 808"), as applicable. The terms of these arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D expenses. Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to the customer which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.



*License Fees:* If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. We evaluate the measure of progress each at reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

*Milestone Payments:* At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses or participate in the cost sharing of such R&D expenses. Such reimbursements and cost sharing arrangements have been reflected as a reduction of R&D expense in our condensed consolidated statements of operations, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement or cost sharing of research and development services are recorded as a reduction of R&D expense.

Under the terms of our collaboration agreement with Mylan Ireland Limited ("Mylan") for revefenacin, we are also entitled to a share of US profits and losses (65% Mylan/35% Theravance Biopharma) received in connection with commercialization of revefenacin, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). If and when revefenacin is approved, we expect that Mylan will be the principal in the sales transaction and will record the product sales. For the periods presented, our share of the losses under a co-promote arrangement are recorded within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. See "Note 3. Collaborative Arrangements" for additional information about our collaboration agreement with Mylan.

We adopted ASC 606 on January 1, 2018 using the modified retrospective method. Our prior periods remain reported under ASC 605. Our revenue recognition policy under ASC 605 for the comparative 2017 periods is included in our Annual Report on Form 10-K for the year ended December 31, 2017.

### **Income Taxes**

On January 1, 2018, we adopted ASU 2016-16, *Income Taxes (Topic 740), Intra-Entity Transfers of Assets Other Than Inventory* ("ASU 2016-16") using the modified retrospective approach. ASU 2016-16 requires immediate recognition of income tax consequences of intra-company asset transfers, other than inventory transfers. Legacy GAAP prohibited recognition of income tax consequences of intra-company asset transfers whereby the seller defers any net tax effect and the buyer is prohibited from recognizing a deferred tax asset on the difference between the newly created tax basis of the asset in its tax jurisdiction and its financial statement carrying amount as reported in the consolidated financial statements. An example of an inter-company asset transfers included in ASU 2016-16's scope is intellectual property. The adoption of ASU

2016-16 did not have a material impact on our balance sheet or statement of operations as our deferred tax assets are fully offset by a valuation allowance.

### **Recently Issued Accounting Pronouncements Not Yet Adopted**

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. Based on our initial assessment of ASU 2016-02, we believe that the largest impact to our balance sheet will be from recognizing a right-of-use asset and corresponding lease liability related to our property leases in South San Francisco and Dublin, Ireland. We expect to adopt ASU 2016-02 in the first quarter of 2019, and we are continuing to evaluate the full impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

We have evaluated other recently issued accounting pronouncements and do not believe that any of these pronouncements will have a 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 of 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 ordinary shares had been issued for other dilutive securities.

For the three months ended March 31, 2018 and 2017, diluted and basic net loss per share was identical since potential ordinary shares were excluded from the calculation, as their effect was anti-dilutive.

### *Anti-dilutive Securities*

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

| <b>(In thousands)</b>   | <b>Three Months Ended<br/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2018</b>                             | <b>2017</b> |
| Share issuances under equity incentive plans and ESPP           | 3,916                                   | 3,386       |
| Restricted shares   | 5                                       | 26          |
| Share issuances upon the conversion of convertible senior notes | 6,676                                   | 6,676       |
| Total   | 10,597                                  | 10,088      |

In addition, there were 1,305,000 shares that are subject to performance-based vesting criteria which have been excluded from the ordinary equivalent shares table above as of March 31, 2018 and 2017, respectively.

## **3. Collaborative Arrangements**

### **Revenue from Collaborative Arrangements**

We recognized revenues from our collaborative arrangements as follows:

| <b>(In thousands)</b>                         | <b>Three Months Ended<br/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2018</b>                             | <b>2017</b> |
| Janssen                                       | \$ 4,613                                | \$ —        |
| Other   | 27                                      | 37          |
| Total revenue from collaborative arrangements | \$ 4,640                                | \$ 37       |

Under legacy ASC 605 revenue guidance, we would have recognized \$4.7 million in revenue from collaboration arrangements for the three months ended March 31, 2018.

### **Changes in Deferred Revenue Balances**

We recognized the following revenue as a result of changes in our deferred revenue balance during the period below:

| <b>(In thousands)</b>   | <b>Three Months Ended</b> |
|---|---------------------------|
|   | <b>March 31,</b>          |
|   | <b>2018</b>               |
| <b>Revenue recognized in the period from:</b>                       |                           |
| Amounts included in deferred revenue at the beginning of the period | \$ 16                     |

### **Mylan**

#### *Development and Commercialization Agreement*

In January 2015, Mylan Ireland Limited (“Mylan”) and we established a strategic collaboration for the development and, subject to regulatory approval, commercialization of revefenacin (TD-4208), our investigational LAMA in development for the treatment of COPD (the “Mylan Agreement”). 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.

Under the Mylan Agreement, Mylan paid us an up-front fee of \$15.0 million for the delivery of the revefenacin license in 2015 and, in 2016, Mylan paid us a milestone payment \$15.0 million for the achievement of 50% enrollment in the Phase 3 twelve-month safety study. Separately, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., 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, equal to \$4.2 million, over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015.

As of March 31, 2018, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to sales milestones based on achieving certain levels of net sales and \$10.0 million relates to regulatory actions in the European Union (“EU”).

We evaluated the terms of the Mylan Agreement under ASC 606 and identified two performance obligations: (1) delivery of the license to develop and commercialize revefenacin; and (2) joint steering committee participation. We determined the license to be distinct from the joint steering committee participation. We further determined that the transaction price under the arrangement was comprised of the following: (1) \$15.0 million up-front license fee received in 2015; (2) \$4.2 million premium related to the ordinary share purchase agreement received in 2015; and (3) \$15.0 million milestone for 50% enrollment in the Phase 3 twelve-month safety study received in 2016. The total transaction price of \$34.2 million was allocated to the two performance obligations based on our best estimate of the relative stand-alone selling price. For the delivery of the license, we based the stand-alone selling price on a discounted cash flow approach and considered several factors including, but not limited to: discount rate, development timeline, regulatory risks, estimated market demand and future revenue potential. For the committee participation, we based the stand-alone selling price on the average compensation of our committee members estimated to be incurred over the performance period. We expect to recognize revenue from the committee participation ratably over the performance period of approximately seventeen years.

The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained under ASC 606. As part of our evaluation of the development and regulatory milestones constraint, we determined that the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within our control and uncertain at this stage. We expect that the sales-based milestone payments and

royalty arrangements will be recognized when the sales occur or the milestone is achieved. We will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

Under the terms of the Mylan Agreement, Mylan is responsible for reimbursement of our costs related to the registrational program up until the approval of the first new drug application. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are recognized proportionately with the performance of the underlying services and accounted for as reductions to R&D expense. For this unit of account, we do not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

We are also entitled to a share of US profits and losses (65% Mylan/35% Theravance Biopharma) received in connection with commercialization of revefenacin, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). We expect that Mylan will be the principle in the sales transaction and will record the product sales. Under a co-promote arrangement with Mylan, we currently record losses in the period incurred based on our estimate of those amounts. Until revefenacin is approved and we have recognized a profit under the agreement, losses are recognized within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. For this unit of account, we have determined that Mylan is not a customer and do not analogize to ASC 606 for the profits and losses sharing activities. These activities are considered to be collaborative activities under the scope of ASC 808, and we will recognize the shared profits and losses in the periods that such profits and losses occur.

As of March 31, 2018, \$0.3 million was recorded in deferred revenue on the condensed consolidated balance sheet under the Mylan Agreement. This amount reflects revenue allocated to joint steering committee participation and will be recognized as revenue over the course of the remaining performance period of approximately fourteen years. For the three months ended March 31, 2018, we recognized \$6,000 in revenue primarily from the recognition of previously deferred revenue.

### ***Janssen Biotech***

In February 2018, we entered into a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn’s disease (the “Janssen Agreement”). Under the terms of the Janssen Agreement, we received an upfront payment of \$100.0 million. In 2018, we plan to initiate a large, Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis with TD-1473, as well as a Phase 2 study in Crohn’s disease. Following completion of the Phase 2 Crohn’s study and the Phase 2b induction portion of the ulcerative colitis study, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of \$200.0 million. Upon such election, we and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases and share profits in the US and expenses related to a potential Phase 3 program (67% to Janssen; 33% to Theravance Biopharma). We would receive royalties on ex-US sales at double-digit tiered percentage royalty rates, and we would be eligible to receive up to an additional \$700.0 million in development and commercialization milestone payments from Janssen.

We evaluated the terms of the Janssen Agreement under ASC 606 and identified research and development activities as our only performance obligation. We further determined that the transaction price under the arrangement was the \$100.0 million upfront payment which was allotted to the single performance obligation.

The \$900.0 million in future potential payments is considered variable consideration if Janssen elects to remain in the collaboration arrangement following completion of certain Phase 2 activities, as described above and, as such, was not included in the transaction price, as the potential payments were all determined to be fully constrained under ASC 606. As part of our evaluation of this variable consideration constraint, we determined that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of our control. We expect that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

For the three months ended March 31, 2018, we recognized \$4.6 million as revenue from collaboration agreements related to the Janssen Agreement. The remaining transaction price of \$95.4 million was recorded in deferred revenue on the condensed consolidated balance sheet and is expected to be recognized as revenue as the research and development services

are delivered over the Phase 2 period. Revenue is recognized for the research and development services based on a measure of our efforts toward satisfying a performance obligation relative to the total expected efforts or inputs to satisfy the performance obligation (e.g., costs incurred compared to total budget). In future reporting periods, we will revisit our estimates related to our efforts towards satisfying the performance obligation and may record a change in estimate.

### **Alfasigma**

#### *Development and Collaboration Agreement*

Under an October 2012 development and collaboration agreement for velusetrag, we and Alfasigma S.p.A (“Alfasigma”) agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal) (the “Alfasigma Agreement”). As part of the Alfasigma Agreement, Alfasigma funded the majority of the costs associated with the Phase 2 gastroparesis program, which consisted of a Phase 2 study focused on gastric emptying and a Phase 2 study focused on symptoms. Alfasigma had an exclusive option to develop and commercialize velusetrag in the EU, Russia, China, Mexico and certain other countries, while we retained full rights to velusetrag in the US, Canada, Japan and certain other countries.

In late April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag, and we elected not to pursue further development of velusetrag. As a result, we will transfer global rights for velusetrag to Alfasigma under the terms of the existing collaboration agreement. We have received a \$10.0 million option fee from Alfasigma, and we are eligible to receive future potential development, regulatory and sales milestone payments and royalties.

As of March 31, 2018, we evaluated the terms of the Alfasigma Agreement under ASC 606 and identified committee participation as our only performance obligation. We further determined that the transaction price under the arrangement was nil, as of March 31, 2018, as any potential development or regulatory milestones were determined to be fully constrained as prescribed under ASC 606. As part of our evaluation of this variable consideration constraint, we determined that the potential payments are contingent upon development and regulatory milestones that are uncertain and are highly susceptible to factors outside of our control. In addition, we expect that any consideration related to sales-based milestones would be recognized when the subsequent sales occur.

#### **Reimbursement of R&D Expense**

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D expense. Activities under collaborative arrangements for which we are entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, we do not analogize to ASC 606 or recognize revenue. We record reimbursement payments received from our collaboration partners as reductions to R&D expense.

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

| <b>(In thousands)</b>                     | <b>Three Months Ended<br/>March 31,</b> |                 |
|---|---|-----------------|
|   | <b>2018</b>                             | <b>2017</b>     |
| <b>Mylan</b>                              | <b>\$ 1,850</b>                         | <b>\$ 7,089</b> |
| <b>Other</b>                              | <b>—</b>                                | <b>37</b>       |
| <b>Total reduction to R&amp;D expense</b> | <b>\$ 1,850</b>                         | <b>\$ 7,126</b> |

#### 4. Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amount shown on the condensed consolidated statements of cash flows.

| (In thousands)   | March 31,  |            |
|--|------------|------------|
|  | 2018       | 2017       |
| Cash and cash equivalents  | \$ 125,831 | \$ 169,945 |
| Restricted cash  | 833        | 833        |
| Total cash, cash equivalents, and restricted cash shown on the condensed consolidated statements of cash flows | \$ 126,664 | \$ 170,778 |

Restricted cash pertained to certain lease agreements and letters of credit where we have pledged cash and cash equivalents as collateral. The cash-related amounts reported in the table above exclude our investments in short and long-term marketable securities that are reported separately on the condensed consolidated balance sheets.

#### 5. Investments and Fair Value Measurements

##### Available-for-Sale Securities

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.

Available-for-sale securities are summarized below:

| (In thousands)                  |         | March 31, 2018 |                        |                         |                      |
|---------------------------------|---------|----------------|------------------------|-------------------------|----------------------|
|                                 |         | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| US government securities        | Level 1 | \$ 99,833      | \$ —                   | \$ (372)                | \$ 99,461            |
| US government agency securities | Level 2 | 37,187         | —                      | (89)                    | 37,098               |
| Corporate notes                 | Level 2 | 120,945        | 1                      | (383)                   | 120,563              |
| Commercial paper                | Level 2 | 73,523         | —                      | (11)                    | 73,512               |
| Marketable securities           |         | 331,488        | 1                      | (855)                   | 330,634              |
| Money market funds              | Level 1 | 73,184         | —                      | —                       | 73,184               |
| Total                           |         | \$ 404,672     | \$ 1                   | \$ (855)                | \$ 403,818           |

  

| (In thousands)                  |         | December 31, 2017 |                        |                         |                      |
|---------------------------------|---------|-------------------|------------------------|-------------------------|----------------------|
|                                 |         | Amortized Cost    | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| US government securities        | Level 1 | \$ 89,896         | \$ —                   | \$ (342)                | \$ 89,554            |
| US government agency securities | Level 2 | 50,891            | —                      | (113)                   | 50,778               |
| Corporate notes                 | Level 2 | 141,226           | 2                      | (280)                   | 140,948              |
| Commercial paper                | Level 2 | 19,893            | —                      | —                       | 19,893               |
| Marketable securities           |         | 301,906           | 2                      | (735)                   | 301,173              |
| Money market funds              | Level 1 | 69,055            | —                      | —                       | 69,055               |
| Total                           |         | \$ 370,961        | \$ 2                   | \$ (735)                | \$ 370,228           |

As of March 31, 2018, all of the marketable securities had contractual maturities within two years and the weighted average maturity of the marketable securities was approximately six 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 months ended March 31, 2018.

In general, we invest in debt securities with the intent to hold such securities until maturity at par value. We do not intend to sell the investments that are currently 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, as of March 31, 2018, were temporary in nature. There were no material unrealized losses on investments which have been in a loss position for more than twelve months as of March 31, 2018.

As of March 31, 2018, our accumulated other comprehensive loss on our condensed consolidated balance sheets consisted of net unrealized losses on available-for-sale investments. During the three months ended March 31, 2018, we did not sell any of our marketable securities.

#### *Long-term Debt Fair Value*

We have \$230.0 million of 3.25% convertible senior notes (“Notes”) outstanding as of March 31, 2018 with an estimated fair value of \$234.0 million. The estimated fair value was primarily based upon the underlying price of Theravance Biopharma’s publicly traded shares and other observable inputs as of March 31, 2018. The inputs to determine fair value of the Notes are categorized as Level 2 inputs. Level 2 inputs include quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

### **6. Theravance Respiratory Company, LLC**

Prior to the spin-off from Innoviva, our former parent company, (the “Spin-Off”) Innoviva assigned to Theravance Respiratory Company, LLC (“TRC”), a Delaware limited liability company formed by Innoviva, its strategic alliance agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Through our 85% equity interests in TRC, we are entitled to receive 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 drug programs assigned to TRC include Trelegy Ellipta 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.

On May 31, 2014, we entered into the TRC LLC Agreement with Innoviva that governs the operation of TRC. Under the TRC LLC Agreement, Innoviva is the manager of TRC, and the business and affairs of TRC are managed exclusively by the manager, including (i) day to day management of the drug programs in accordance with the existing GSK agreements, (ii) preparing an annual operating plan for TRC and (iii) taking all actions necessary to ensure that the formation, structure and operation of TRC complies with applicable law and partner agreements. We are responsible for our proportionate share of TRC’s administrative expenses incurred by Innoviva.

We analyzed our ownership, contractual and other interests in TRC to determine if it is a variable-interest entity (“VIE”), whether we have a variable interest in TRC and the nature and extent of that interest. We determined that TRC is a VIE. The party with the controlling financial interest, the primary beneficiary, is required to consolidate the entity determined to be a VIE. Therefore, we also assessed whether we are the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and our obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on our assessment, we determined that we are not the primary beneficiary of TRC, and, as a result, we do not consolidate TRC in our consolidated financial statements. TRC is recognized on our consolidated financial statements under the equity method of accounting, and the value of our equity investment in TRC was not material for the periods presented.

For the three months ended March 31, 2018, we recognized \$0.7 million in Interest and other income on our condensed consolidated statements of operations which represented our share in the net income of TRC which was generated by royalty payments from GSK to TRC arising from the net sales of Trelegy Ellipta. There was no income from TRC in the comparable prior year period.



## 7. Inventories

Inventory consists of the following:

| <u>(In thousands)</u> | <u>March 31,<br/>2018</u> | <u>December 31,<br/>2017</u> |
|-----------------------|---------------------------|------------------------------|
| Raw materials         | \$ 10,611                 | \$ 11,729                    |
| Work-in-process       | 1,986                     | 66                           |
| Finished goods        | 4,620                     | 5,035                        |
| Total inventories     | <u>\$ 17,217</u>          | <u>\$ 16,830</u>             |

## 8. 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:

| <u>(In thousands)</u>                  | <u>Three Months Ended<br/>March 31,</u> |                  |
|--|---|------------------|
|  | <u>2018</u>                             | <u>2017</u>      |
| Research and development               | \$ 6,559                                | \$ 5,101         |
| Selling, general and administrative    | 7,439                                   | 5,168            |
| Total share-based compensation expense | <u>\$ 13,998</u>                        | <u>\$ 10,269</u> |

### *Performance-Contingent Awards*

In the first quarter of 2016, the Compensation Committee of our 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. The vesting of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. The goals that must be met in order for the performance-contingent RSAs and RSUs to vest are strategically important for the Company, and the Compensation Committee believes the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment. As of March 31, 2018 and 2017, there were 1,305,000 performance-contingent RSAs and 135,000 performance-contingent RSUs outstanding.

Expense associated with these awards is broken into three separate tranches and may 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 is reassessed at each quarter-end reporting period. The maximum potential expense associated with the awards could be up to \$35.5 million (allocated as \$13.3 million for research and development expense and \$22.2 million for selling, general and administrative expense) if all of the performance conditions are achieved.

For the three months ended March 31, 2018, we recognized \$1.1 million and \$0.9 million of share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first and second tranches of these awards, respectively, was considered to be probable of vesting. For the three months ended March 31, 2017, we recognized \$0.4 million of share-based compensation expense related to our assessment of the probability that the performance conditions associated with the first tranche was considered to be probable of vesting. As of March 31, 2017, the second tranche was not considered probable of vesting. As of March 31, 2018 and 2017, we determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to the third tranche has been recognized to date.

In the third quarter of 2017, the Compensation Committee approved the grant of 50,000 performance contingent RSUs to a newly appointed member of senior management. The RSUs have dual triggers of vesting based upon the achievement of certain corporate operating milestones in specified timelines, as well as a requirement for continued



employment. Share-based compensation expense related to this grant is broken into two separate tranches and recognized when the associated performance goals are deemed to be probable of achievement. The maximum expense associated with the first tranche is \$0.8 million. In 2017, we recognized \$0.4 million in share-based compensation expense as we determined that the performance conditions associated with the first tranche was probable of vesting, and during the three months ended March 31, 2018, we recognized the remaining \$0.4 million of share-based compensation expense as the performance conditions associated with the first tranche of this award were met. We have determined that the second tranche was not probable of vesting as of March 31, 2018 and, as a result, no compensation expense related to the second tranche has been recognized to date.

## **9. Income Taxes**

The income tax provision was \$0.1 million and \$5.4 million for the three months ended March 31, 2018 and 2017, respectively, although we incurred operating losses on a consolidated basis. The provision for income tax was primarily due to recording contingent tax liabilities pertaining primarily to uncertain tax positions taken with respect to transfer pricing and tax credits. 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. As of March 31, 2018, 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 was 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 US as compared with other regions in the world, and changes in overall levels of income before tax.

### ***US Tax Reform***

On December 22, 2017, the US government enacted the Tax Cuts and Jobs Acts (the "Tax Act"). The Tax Act significantly revises the US corporate income tax laws by, amongst other things, reducing the corporate income tax rate from 35% to 21% and implementing a modified territorial tax system that includes a one-time repatriation tax on accumulated undistributed foreign earnings.

Based on provisions of the Tax Act, we remeasured the deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The estimated amount of the remeasurement of our federal deferred tax balance was \$12.4 million. However, as we recognize a valuation allowance on deferred tax assets, if it is more likely than not that the assets will not be realized in future years, there is no impact to effective tax rate, as any change to deferred taxes would be offset by valuation allowances.

The changes included in the Tax Act are broad and complex. The final transition impact of the Tax Act may differ from the above estimate, possibly materially, due to, among other things, changes in interpretations of the Tax Act, any legislative action to address questions that arise because of the Tax Act, any changes in accounting standards for income

taxes or related interpretations in response to the Tax Act, or any updates or changes to estimates the Company has utilized to calculate the transition impact, including impact from changes to current year earnings estimates and foreign exchange rates of foreign subsidiaries. For example, one area where we are waiting on further guidance before finalizing our conclusion as to the impact of the Tax Act on our deferred tax assets and liabilities is the transition rules with respect to the tax deductibility of executive compensation. The Securities Exchange Commission has issued rules that would allow for a measurement period of up to one year after the enactment date of the Tax Act to finalize the recording of the related tax impacts. For the three months ended March 31, 2018, we did not adjust or include any previously assessed Tax Act effect in our quarterly tax provision. We currently anticipate finalizing and recording any resulting adjustments by December 22, 2018.

## 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, 2017. 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 help improve the lives of patients suffering from serious illness.

In our relentless pursuit of this objective, we strive to apply insight and innovation at each stage of our business, including research, development and commercialization, and utilize both internal capabilities and those of partners around the world. Our research efforts are focused in the areas of inflammation and immunology. Our research goal is to design localized medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing localized medicines for the lungs to treat respiratory disease. The first potential medicine to emerge from our research focus on immunology and localized treatments is an oral, intestinally restricted pan-Janus kinase (JAK) inhibitor, currently in development to treat a range of inflammatory intestinal diseases. Our pipeline of internally discovered product candidates will continue to evolve with the goal of creating transformational medicines to address the significant needs of patients.

In addition, we have an economic interest in future payments that may be made by Glaxo Group or one of its affiliates (GSK) pursuant to its agreements with Innoviva, Inc. relating to certain programs, including Trelegy Ellipta.

### Program Highlights

#### *Intestinally Restricted Pan-Janus Kinase (JAK) Inhibitor Program (TD-1473)*

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 and myelofibrosis and have demonstrated therapeutic benefit for

patients with ulcerative colitis. However, these products are known to have side effects based on their systemic exposure. Our goal is to develop an orally administered, intestinally restricted pan-JAK inhibitor specifically designed to distribute adequately and predominantly to the tissues of the intestinal tract, treating inflammation in those tissues while minimizing systemic exposure. We are focused on utilizing targeted JAK inhibitors for potential treatment of a range of inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. TD-1473 is our lead intestinally restricted pan-JAK inhibitor that is progressing into multiple clinical studies in 2018, as further described below. TD-3504 is a back-up compound that has successfully completed Phase 1 studies in healthy volunteers. Development of TD-3504 has been paused, consistent with the strategy we generally apply to back-up compounds and due to our significant investments in TD-1473.

#### *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, including the determination of 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 were significantly lower than the plasma exposure of tofacitinib.

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 clinical progression of the compound.

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, in contrast to tofacitinib, TD-1473 did not reduce systemic immune cell counts. Also, we completed six and nine month toxicology studies of TD-1473 and demonstrated favorable safety margins in these studies, in support of the dose ranges planned in the Phase 3 registrational program. Based on these preclinical findings, we believe that TD-1473 represents a potential breakthrough approach to treating inflammatory intestinal diseases without the risk generally associated with systemically active therapies.

#### *Phase 1b Study*

In late 2016, we announced dosing of the first patient in a Phase 1b clinical study of TD-1473 in patients with moderate to severe ulcerative colitis. The Phase 1b exploratory study in 40 patients was designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of TD-1473 over a 28-day treatment period. In addition, the study incorporates biomarker analysis and clinical, endoscopic, and histologic assessments to evaluate biological effect.

In August 2017, we announced encouraging data from the first cohort of patients in the Phase 1b study. Data from the first cohort demonstrated evidence of localized biological activity for TD-1473 after four weeks of treatment, based on a compilation of clinical, endoscopic, and biomarker assessments. Pharmacokinetic data demonstrated minimal systemic exposure, and there was no evidence of systemic immunosuppression.

#### *Janssen Biotech Collaboration*

In February 2018, we announced a global co-development and commercialization agreement with Janssen Biotech, Inc. ("Janssen") for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. Under the terms of the agreement, we received an upfront payment of \$100.0 million and will be eligible to receive up to an additional \$900.0 million in potential payments, if Janssen elects to remain in the collaboration following the completion of certain Phase 2 activities. Upon such election, we and Janssen will jointly develop and commercialize TD-1473 in inflammatory intestinal diseases, and we and Janssen will share profits and losses in the US and

expenses related to a potential Phase 3 program (67% to Janssen; 33% to us). In addition, we would receive royalties on ex-US sales at double-digit tiered percentage royalty rates.

In 2018, we plan to initiate a large, Phase 2b/3 adaptive design induction and maintenance study in ulcerative colitis with TD-1473, as well as a Phase 2 study in Crohn's disease. Following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study, Janssen can elect to obtain an exclusive license to develop and commercialize TD-1473 and certain related compounds by paying us a fee of \$200.0 million. The closing of this portion of the transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"). After Phase 2, Janssen would lead subsequent development of TD-1473 in Crohn's disease if it makes such election. We will lead development of TD-1473 in ulcerative colitis through completion of the Phase 2b/3 program. If TD-1473 is commercialized, we have the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US.

#### ***TD-9855***

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor ("NSRI"). TD-9855 completed a Phase 2 study in patients with fibromyalgia, demonstrating statistically significant and clinically meaningful improvements in pain and core symptoms at the highest dose tested compared to placebo.

We are assessing the potential use of TD-9855 in neurogenic orthostatic hypotension ("nOH"), and in May 2016, we initiated an exploratory Phase 2a study of TD-9855 in this indication. The Phase 2a study was designed to evaluate postural changes in blood pressure, symptom reduction, and safety and tolerability of single ascending doses in patients with nOH.

Based on encouraging treatment responses in the first part of the study, we announced in February 2017 our plan to amend the study design to allow those patients who respond to continue dosing for up to 20 weeks to assess the durability of their response. We believe the ability to demonstrate a durable effect in nOH could lead to significant benefits for patients over existing therapy. Given many nOH patients suffer from underlying conditions that can cause rapid deterioration of their health, the endpoints of the extended dosing portion of the study evaluate patient responses following 4 weeks of therapy. We expect data from the extended Phase 2a study by the end of July.

In parallel with the Phase 2a study, we are seeking regulatory support for an orphan drug designation and an expedited development pathway for TD-9855 in nOH.

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

Revefenacin is an investigational long-acting muscarinic antagonist ("LAMA") under regulatory review for the treatment of COPD, with an FDA PDUFA target action date in November of 2018. 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 US 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 ("MDI/DPI") 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. Mylan funded the Phase 3 development program, enabling us 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 are co-developing nebulized revefenacin for COPD and other respiratory diseases. We are leading the US Phase 3 development program, and Mylan is responsible for reimbursement of our costs related to the registrational program up until the approval of the first new drug application (“NDA”), after which costs will be shared. If a product developed under the collaboration is approved in the US, Mylan will lead commercialization, and we retain the right to co-promote the product in the US under a profit and loss sharing arrangement (65% Mylan/35% Theravance Biopharma). Currently, we plan to co-promote revefenacin with Mylan in the US, and we are working diligently, together with Mylan, to prepare for the anticipated launch. Outside the US (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.

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. In February 2016, we earned a \$15.0 million development milestone payment for achieving 50% enrollment in the Phase 3 twelve-month safety study. As of March 31, 2018, we are eligible to receive from Mylan additional potential development, regulatory and sales milestone payments totaling up to \$205.0 million in the aggregate, with \$160.0 million associated with revefenacin monotherapy and \$45.0 million for future potential combination products. Of the \$160.0 million associated with monotherapy, \$150.0 million relates to sales milestones based on achieving certain levels of net sales and \$10.0 million relates to regulatory actions in the European Union (“EU”). We do not expect to earn any milestone payments from Mylan in 2018.

We retain worldwide rights to revefenacin delivered through other dosage forms, such as a 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. In China, we retain all rights to revefenacin in any dosage form.

#### *Phase 3 Study in COPD and NDA Submission*

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 included two replicate three-month efficacy studies and a single twelve-month safety study. The two efficacy studies examined two 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 were 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 was an open-label, active comparator study of 12 months duration.

In October 2016, we announced positive top-line results from the two replicate Phase 3 efficacy studies of revefenacin in more than 1,200 moderate to very severe COPD patients, and in May and November 2017 we reported additional data from these studies. Both Phase 3 efficacy studies met their primary endpoints, demonstrating statistically significant improvements over placebo in trough FEV1 after 12 weeks of dosing for each of the revefenacin doses studied (88 mcg once daily and 175 mcg once daily). The studies also demonstrated that the 88 mcg and 175 mcg doses of revefenacin were generally well-tolerated, with comparable rates of adverse events and serious adverse events across all treatment groups (active and placebo). In July 2017, we announced positive top-line results from the twelve-month safety study in more than 1,000 COPD patients. Data demonstrated that both the 88 mcg and 175 mcg doses of revefenacin were generally well-tolerated, with low rates of adverse events (AEs) and serious adverse events (SAEs), comparable to those seen with the active comparator. Together, the three studies enrolled approximately 2,280 patients.

In November 2017, we submitted to the FDA for filing a NDA for revefenacin supported by data from the two replicate Phase 3 efficacy studies and twelve-month safety study. In January 2018, the FDA accepted the NDA for filing and assigned a PDUFA target action date of November 13, 2018.

### *Phase 3b PIFR Study*

In March 2017, we initiated a Phase 3b study of revefenacin in patients with suboptimal peak inspiratory flow rate (“PIFR”). This study is not required for NDA approval and was designed to support commercialization, if revefenacin is approved. The purpose of the study was to assess whether nebulized revefenacin was superior to handheld tiotropium (dosed via the Handihaler® device) in a broad population of COPD patients with suboptimal PIFR. The primary endpoint was improvement in lung function, as measured by trough forced expiratory volume in one second (FEV<sub>1</sub>) after 4 weeks of treatment.

The PIFR study was completed in the first quarter of 2018. In the overall population of approximately 200 moderate to very severe (GOLD Stage 2/3/4) COPD patients, we saw numerical improvements for revefenacin over tiotropium, but these improvements were not statistically significant, and as a result the study failed to meet the predefined threshold for superiority. In the pre-specified subgroup of severe and very severe (GOLD 3/4) COPD patients, which represented approximately 80% of the patients in the study, revefenacin demonstrated nominally statistically significant and clinically relevant improvements in trough FEV<sub>1</sub> versus tiotropium. Data generated in the study provide important insights to inform future potential studies of revefenacin in COPD patients with suboptimal PIFR. Revefenacin was well tolerated in this study, with no new safety issues identified. The Company plans to publish the results from this study in a future medical meeting or publication.

### ***Velusetrag (TD-5108)***

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-HT<sub>4</sub> receptor. We are partnered in the development of velusetrag and its commercialization in certain countries with Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.). In April 2014, we announced 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.

In August 2017, we announced positive top-line results from a 12-week, Phase 2b study of velusetrag characterizing the impact on symptoms and gastric emptying of three oral doses of velusetrag (5, 15 and 30 mg) compared to placebo administered once daily over 12 weeks of therapy. Results from the study demonstrated statistically significant improvements in gastroparesis symptoms and gastric emptying for patients receiving 5 mg of velusetrag as compared to placebo. Patients in the 15 and 30 mg velusetrag study arms demonstrated statistically significant improvements in gastric emptying, but they did not experience statistically significant improvements in gastroparesis symptoms. Velusetrag was shown to be generally well-tolerated, with 5 mg and placebo having comparable rates of adverse events and serious adverse events. Completion of the Phase 2b study was followed by dialogue with regulatory authorities in the US and EU regarding further development of velusetrag.

In late April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag. As a result, we received a \$10.0 million option fee. Additionally, we elected not to pursue further development of velusetrag, based on our planned pipeline investments and in light of the current FDA requirement that a chronically administered gastroparesis product in this class complete a large Phase 3 safety study. Global rights to develop, manufacture and commercialize velusetrag will transfer to Alfasigma under the terms of the existing collaboration agreement. Under the terms of the collaboration with Alfasigma, we are now entitled to receive future potential development, regulatory and commercial milestone payments of up to \$26.8 million, and tiered royalties on global net sales ranging from high single digits to the mid-teens.

### ***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 US 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. In addition, in 2016, the Food and Drug Administration (“FDA”) allowed us to add new clinical



data to the VIBATIV label concerning concurrent bacteremia in cases of HABP/VABP and cSSSI. VIBATIV is also indicated in Canada and Russia for cSSSI and HABP and VABP caused by Gram-positive bacteria, including MRSA.

Our acute care sales force markets VIBATIV in the US, and we maintain an independent marketing and medical affairs team. This same organization will support revefenacin, if approved in the US, alongside our partner for the program. Outside of the US, our strategy is to market VIBATIV through a network of partners. To date, we have secured partners for VIBATIV in the following geographies: Canada, Middle East and North Africa, Israel, Russia, China and India. In 2016, we and Clinigen reached a mutual decision for Clinigen to return to us the commercial rights to market and distribute VIBATIV in the EU. We do not intend to commercialize VIBATIV in the EU without a partner, and we have been unable to secure another such partner. Accordingly, in early 2018 we filed a withdrawal notice with the European Medicines Agency (“EMA”), and this notice was approved, thus extinguishing VIBATIV’s EU marketing authorization.

Given the challenges we have faced commercializing VIBATIV in the US in a highly competitive environment against a variety of generic drugs, we have reduced and are closely managing our overall spending related to the product while preparing for and investing in the potential commercial launch of revefenacin as a treatment for COPD. We continue to view VIBATIV as an important medicine to treat serious infections in very sick patients, and we intend to continue to support the product.

#### *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.

In February 2018, the study stopped enrolling new patients following an interim analysis conducted by an independent review committee and company-wide review of investment priorities. The committee concluded the study was underpowered and therefore unlikely to achieve the primary study objective, without a significant increase in study size beyond the planned sample size of approximately 250 patients. Given the incremental investment required, we elected to close the study. No new safety issues were identified in the study, and as a result patients previously enrolled are allowed to complete dosing. We plan to submit data generated from the study for future scientific publication.

#### *Telavancin Observational Use Registry (“TOUR™”) Study*

Initiated in February 2015, the 1,000-patient TOUR™ 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 effectiveness and safety outcomes in medical practice, we aim to create an expansive knowledge base to guide clinical use and future development of the drug. Data from this study is providing information about the use of VIBATIV in real-world clinical settings, including reports of positive clinical responses in patients with bacteremia, endocarditis, osteomyelitis, skin and respiratory infections. During 2017, we concluded the TOUR™ registry study and completed the data base. We have begun and plan to continue to analyze the data and publish in a number of areas reflecting real world use of VIBATIV at future medical meetings and medical journals.

#### *Janssen Pharmaceutica License Agreement*

In 2002, we entered into a License Agreement with Janssen Pharmaceutica N.V. (“Janssen Pharmaceutica”) pursuant to which we have licensed rights under certain patents owned by Janssen Pharmaceutica covering an excipient used in the formulation of telavancin. Pursuant to the terms of this license agreement, we are obligated to pay royalties to Janssen Pharmaceutica of 2.5% to 5% of any net commercial sales of VIBATIV (telavancin). The license will terminate in 2019 on the later of 10 years from first commercial sale of VIBATIV and the date of expiration of the last applicable Janssen Pharmaceutica patent covering VIBATIV. The license is terminable by us upon prior written notice to Janssen Pharmaceutica or upon an uncured breach or a liquidation event of one of the parties.



### ***Neprilysin (NEP) Inhibitor Program (TD-0714 and TD-1439)***

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 for this program 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 aim to create a platform for multiple combination products with our NEP inhibitor with features that are differentiated from currently available products. Our NEP inhibitor program consists of two compounds (TD-0714 and TD-1439), each of which demonstrated characteristics in line with our target product profile in Phase 1 studies in healthy volunteers.

#### *TD-0714*

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

In March 2016, we completed a Phase 1 randomized, double-blind, placebo-controlled, single ascending dose (“SAD”) study in healthy volunteers of our most advanced NEP inhibitor compound, TD-0714. 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 tolerability profile.

In October 2016, we completed a Phase 1 randomized, double-blind, placebo-controlled, multiple ascending dose (“MAD”) study in healthy volunteers of TD-0714. The findings from the MAD study were consistent with the Phase 1 randomized, double-blind, placebo-controlled, SAD study in healthy volunteers we completed in March 2016, demonstrating sustained target engagement, low levels of renal elimination, and a favorable tolerability profile.

#### *TD-1439*

TD-1439 is a second NEP inhibitor compound, which is structurally distinct from TD-0714. In the first half of 2017, we announced favorable results from Phase 1 SAD and a Phase 1 MAD studies of TD-1439. In both Phase 1 studies, TD-1439 demonstrated characteristics which met our target product profile, including sustained 24-hour target engagement, low levels of renal elimination and a favorable tolerability profile.

We are evaluating next steps for both compounds in our NEP inhibitor program clinical program. The results from the Phase 1 programs provide confidence for pursuing future efficacy studies of either compound in a broad range of cardiovascular and renal diseases, including in patients with compromised renal function.

### ***Selective 5-HT<sub>4</sub> Agonist (TD-8954)***

#### *Takeda Collaborative Arrangement*

In June 2016, we entered into a License and Collaboration Agreement with Millennium Pharmaceuticals, Inc., a Delaware corporation (“Millennium”) (the “Takeda Agreement”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954), a selective 5-HT<sub>4</sub> receptor agonist. 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”). TD-8954 is being developed 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 FDA Fast Track designation. Under the terms of the Takeda Agreement, Takeda will be responsible for worldwide

development and commercialization of TD-8954. We received an upfront cash payment of \$15.0 million and will be eligible to receive success-based development, regulatory and sales milestone payments by Takeda. The first \$110.0 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.

## **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 the GSK-Partnered Respiratory Programs, which Innoviva partnered with GSK and assigned to Theravance Respiratory Company, LLC (“TRC”) in connection with Innoviva’s separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma. The GSK-Partnered Respiratory Programs consist primarily of the Trelegy Ellipta 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 does not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Trelegy Ellipta and MABA programs is based solely upon publicly available information and may not reflect the most recent developments under the programs.

#### *Trelegy Ellipta (the combination of fluticasone furoate/umeclidinium bromide/vilanterol)*

Trelegy Ellipta is the first treatment 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. Trelegy Ellipta is approved for use in the US and EU for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. We are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales. Those royalties are upward-tiering from 6.5% to 10%, resulting in cash flows to Theravance Biopharma of approximately 5.5% to 8.5% of worldwide net sales of Trelegy Ellipta. Theravance Biopharma is not responsible for any costs related to Trelegy Ellipta.

Innoviva and GSK conducted two global pivotal Phase 3 studies of Trelegy Ellipta in COPD, the IMPACT study and the FULFIL study.

The IMPACT study, which enrolled 10,355 COPD patients, was initiated in July 2014. In September 2017, GSK and Innoviva disclosed positive headline results from the IMPACT study, in which data demonstrated statistically significant reductions in the annual rate of on-treatment moderate/severe exacerbations for Trelegy Ellipta (100/62.5/25mcg) when compared with two, once-daily dual COPD therapies RELVAR® ELLIPTA®/BREO® ELLIPTA® (FF/VI), an ICS/LABA combination, and ANORO® ELLIPTA® (UMEC/VI), a LAMA/LABA combination. In addition, statistically significant improvements were observed across all pre-specified key secondary endpoints and associated treatment comparisons.

The FULFIL study, which enrolled 1,810 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 Trelegy Ellipta as compared to twice-daily SYMBICORT® TURBOHALER® (budesonide/formoterol) in improving lung function and health-related quality of life, as well as reducing exacerbations in COPD patients.

In September 2017, GSK and Innoviva announced that the US FDA approved Trelegy Ellipta for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. In November 2017, GSK and Innoviva announced the submission of a sNDA to the FDA with data from the IMPACT study to support an expanded label for Trelegy Ellipta. In April 2018, GSK and Innoviva announced the FDA approved the sNDA with an expanded indication for treatment of a broader population of COPD patients with airflow limitation or who have experienced an acute worsening of respiratory symptoms. The new indication is for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. In addition, the FDA removed a boxed warning from Trelegy Ellipta prescribing information.

In December 2017, GSK and Innoviva announced the European Commission granted marketing authorization for Trelegy Ellipta as a maintenance treatment for appropriate patients with COPD.

In February 2018, GSK and Innoviva announced the submission of the IMPACT data to the EMA as part of a type II variation to support an expanded label for Trelegy Ellipta in Europe for the maintenance treatment of moderate to severe COPD. Approval of the submission would mean Trelegy Ellipta, the only once-daily single inhalation triple therapy for the treatment of COPD, could be used by physicians to treat a wider population of patients with the condition who are at risk of an exacerbation and require triple therapy.

Additionally, in December 2016, GSK and Innoviva announced the initiation of the Phase 3 (CAPTAIN) study of Trelegy Ellipta in patients with asthma. The CAPTAIN study is expected to be completed in 2019.

#### *Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)*

GSK961081 ('081), also known as bafenterol, 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.

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, TRC is eligible to receive contingent milestone payments from GSK. The agreements allow for total milestones of up to \$125.0 million for a single-agent medicine and an incremental \$125.0 million for a combination medicine. Of these amounts, \$112.0 million in potential milestones remain for a single-agent medicine, and \$122.0 million remain for a combination medicine. In each case, we would be entitled to receive an 85% economic interest in any such payments.

#### *Theravance Respiratory Company, LLC ("TRC")*

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 by Innoviva. The drug programs assigned to TRC include all Trelegy Ellipta products 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 US 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 policies 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, 2017.

## **Revenue Recognition**

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) using the modified retrospective method. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we identify the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. We then recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

### *Product Sales*

We sell VIBATIV in the US market by making the drug product available through a limited number of distributors, who sell VIBATIV to healthcare providers. Title and risk of loss transfer upon receipt by these distributors. We recognize VIBATIV product sales and related cost of product sales when the distributors obtain control of the drug product, which is at the time title transfers to the distributors.

Product sales are recorded on a net sales basis which includes estimates of variable consideration. The variable consideration results from sales discounts, government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management’s estimates that consider payor mix in target markets, industry benchmarks and experience to date. In general, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

*Sales Discounts:* We offer cash discounts to certain customers as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. In addition, we offer contract discounts to certain direct customers. We estimate sales discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. We account for sales discounts by reducing accounts receivable by the expected discount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

*Chargebacks and Government Rebates:* For VIBATIV sales in the US, we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service (“PHS”), as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such healthcare providers and our expectation about future utilization rates. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payor mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the condensed consolidated balance sheets. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us

the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

*Distribution Fees:* We have contracts with our distributors in the US that include terms for distribution-related fees. We determine distribution-related fees based on a percentage of the product sales price, and we record the distribution fees as an allowance against accounts receivable.

*Product Returns:* We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Our policy is to accept product returns during the six months prior to and twelve months after the product expiration date on product that has been sold to our distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We record our product return reserves as accrued other liabilities.

*Allowance for Doubtful Accounts:* We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2018, there was no allowance for doubtful accounts related to customer payments.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2018.

| <b>(In thousands)</b>                     | <b>Chargebacks,<br/>Discounts and<br/>Fees</b> | <b>Government<br/>and Other<br/>Rebates</b> | <b>Returns</b> | <b>Total</b>    |
|---|--|---|----------------|-----------------|
| Balance at December 31, 2017              | \$ 992   | \$ 352                                      | \$ 947         | \$ 2,291        |
| Provision related to current period sales | 1,482  | 174   | 79             | 1,735           |
| Adjustment related to prior period sales  | (71)   | 73  | (449)          | (447)           |
| Credit or payments made during the period | (1,515)  | (238)                                       | (49)           | (1,802)         |
| Balance at March 31, 2018                 | <u>\$ 888</u>                                  | <u>\$ 361</u>                               | <u>\$ 528</u>  | <u>\$ 1,777</u> |

#### *Collaborative Arrangements*

We enter into collaborative arrangements with partners that fall under the scope of both ASC 606 and Accounting Standards Codification, Topic 808, *Collaborative Arrangements* ("ASC 808"), as applicable. The terms of these arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost sharing of R&D expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against R&D expense. Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include such estimates as, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to the customer which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

*License Fees:* If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from transaction price allocated to the license when the

license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. We evaluate the measure of progress each at reporting period and, if necessary, adjust the measure of performance and related revenue or expense recognition as a change in estimate.

*Milestone Payments:* At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

*Royalties:* For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any material royalty revenue resulting from any of our collaborative arrangements.

Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses or participate in the cost sharing of such R&D expenses. Such reimbursements and cost sharing arrangements have been reflected as a reduction of R&D expense in our condensed consolidated statements of operations, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement or cost sharing of research and development services are recorded as a reduction of R&D expense.

Under the terms of our collaboration agreement with Mylan for revefenacin, we are also entitled to a share of US profits and losses (65% Mylan/35% Theravance Biopharma) received in connection with commercialization of revefenacin, and we are entitled to low double-digit royalties on ex-US net sales (excluding China). If and when revefenacin is approved, we expect that Mylan will be the principal in the sales transaction and will record the product sales. For the periods presented, our share of the losses under the co-promote arrangement are recorded within R&D expense and selling, general and administrative expense on our condensed consolidated statements of operations. See "Note 3. Collaborative Arrangements" for additional information about our collaboration agreement with Mylan.

We adopted ASC 606 on January 1, 2018 using the modified retrospective method. Our prior periods remain reported under Accounting Standards Codification, Topic 605, *Revenue Recognition* ("ASC 605"). Our revenue recognition policy under ASC 605 for the comparative 2017 periods is included in our Annual Report on Form 10-K for the year ended December 31, 2017.

## 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:

| (In thousands)                          | Three Months Ended<br>March 31, |          | Change   |        |
|---|---------------------------------|----------|----------|--------|
|   | 2018                            | 2017     | \$       | %      |
| Product sales                           | \$ 3,679                        | \$ 3,050 | \$ 629   | 21 %   |
| Revenue from collaborative arrangements | 4,640                           | 37       | 4,603    | 12,440 |
| Total revenue                           | \$ 8,319                        | \$ 3,087 | \$ 5,232 | 169 %  |

Revenue from product sales increased by \$0.6 million for the three months ended March 31, 2018, compared to the same period in 2017. The \$0.6 million increase was primarily due to increased VIBATIV sales volume and pricing.

Revenue from collaborative arrangements increased by \$4.6 million for the three months ended March 31, 2018, compared to the same period in 2017. The \$4.6 million increase was primarily attributed to the revenue recognized as part of the \$100.0 million upfront payment from the Janssen collaboration agreement that was entered into in February 2018. The remaining \$95.4 million in deferred revenue is expected to be recognized as revenue as the research and development services are delivered to Janssen over the Phase 2 development period.

### Cost of Goods Sold

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

| (In thousands)     | Three Months Ended March 31, |        | Change |      |
|--------------------|------------------------------|--------|--------|------|
|                    | 2018                         | 2017   | \$     | %    |
| Cost of goods sold | \$ 826                       | \$ 565 | \$ 261 | 46 % |

Cost of goods sold increased by \$0.3 million for the three months ended March 31, 2018, compared to the same periods in 2017. The \$0.3 million increase was primarily due to increased sales volume and manufacturing costs in the current quarter.

### 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<br>March 31, |           | Change   |      |
|---|---------------------------------|-----------|----------|------|
|   | 2018                            | 2017      | \$       | %    |
| Employee-related                                      | \$ 16,795                       | \$ 12,153 | \$ 4,642 | 38 % |
| Share-based compensation                              | 6,559                           | 5,101     | 1,458    | 29   |
| External-related                                      | 14,764                          | 16,256    | (1,492)  | (9)  |
| Facilities, depreciation and other allocated expenses | 9,647                           | 7,055     | 2,592    | 37   |
| Total research & development                          | \$ 47,765                       | \$ 40,565 | \$ 7,200 | 18 % |

R&D expenses increased by \$7.2 million for the three months ended March 31, 2018, compared to the same period in 2017. The increase was primarily attributed to increases in employee-related expenses, share-based compensation, and facilities and other allocated expenses. Increases in such expenses were primarily due to our long-term retention and incentive cash bonus awards granted to certain employees in 2016 which are dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020 and lower employee-related expense reimbursements under certain collaborative arrangements. The increase in facilities and other allocated expenses was primarily due to the extension of our lease of office and laboratory space in South San Francisco, which is amortized on a straight-line basis over the lease term.

Under certain of our collaborative arrangements, we receive partial reimbursement of employee-related costs and external costs, which have been reflected as a reduction of R&D expenses of \$1.9 million and \$7.1 million for the three months ended March 31, 2018 and 2017, respectively. The decrease in expense reimbursements was primarily attributed to the completion of the Phase 3 program and submission of the NDA for revefenacin, a program we are co-developing with Mylan.

### ***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<br>March 31, |           | Change   |      |
|-------------------------------------|---------------------------------|-----------|----------|------|
|                                     | 2018                            | 2017      | \$       | %    |
| Selling, general and administrative | \$ 24,704                       | \$ 20,786 | \$ 3,918 | 19 % |

Selling, general and administrative expenses increased by \$3.9 million for the three months ended March 31, 2018, compared to the same period in 2017. The increase was primarily attributed to increases in general and administrative expenses, including employee-related expenses, share-based compensation, and external-related expenses. The increases in employee-related expenses and share-based compensation were primarily due to our long-term retention and incentive bonus awards granted to certain employees in 2016 which are dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. The increase in external-related expenses was primarily due to an increase in legal and other consulting-related expenses.

### ***Interest Expense***

Interest expense, as compared to the comparable period in the prior year, was as follows:

| (In thousands)   | Three Months Ended March 31, |          | Change |     |
|------------------|------------------------------|----------|--------|-----|
|                  | 2018                         | 2017     | \$     | %   |
| Interest expense | \$ 2,137                     | \$ 2,137 | \$ —   | — % |



Interest expense for the three months ended March 31, 2018 was unchanged, compared to the same period in 2017, and was attributed to the November 2016 issuance of \$230.0 million principal amount of 3.250% convertible senior notes due 2023.

### **Interest and Other Income, net**

Interest and other income, as compared to the comparable period in the prior year, was as follows:

| <b>(In thousands)</b>          | <b>Three Months Ended<br/>March 31,</b> |             | <b>Change</b> |          |
|--------------------------------|---|-------------|---------------|----------|
|                                | <b>2018</b>                             | <b>2017</b> | <b>\$</b>     | <b>%</b> |
| Interest and other income, net | \$ 2,170                                | \$ 1,030    | \$ 1,140      | 111 %    |

Interest and other income for the three months ended March 31, 2018 increased by \$1.1 million, compared to the same period in 2017. The increase was primarily due to \$0.7 million from our share in net income of TRC which was generated by royalty payments from Trelegy Ellipta sales that began in late 2017 and a \$0.4 million increase in interest income and net foreign currency gains in the current quarter.

### **Provision for Income Taxes**

The provision for income taxes, as compared to the comparable period in the prior year, was as follows:

| <b>(In thousands)</b>      | <b>Three Months Ended<br/>March 31,</b> |             | <b>Change</b> |          |
|----------------------------|---|-------------|---------------|----------|
|                            | <b>2018</b>                             | <b>2017</b> | <b>\$</b>     | <b>%</b> |
| Provision for income taxes | \$ 144                                  | \$ 5,383    | \$ (5,239)    | (97)%    |

Our effective tax rate for the three months ended March 31, 2018 was approximately (0.22)%. 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 and tax credits.

### **Liquidity and Capital Resources**

We have financed our operations primarily through public offering of equity and debt securities, private placements of equity, revenue from collaboration arrangements and revenue from product sales. As of March 31, 2018, we had approximately \$435.5 million in cash, cash equivalents, and investments in marketable securities. Also, as of March 31, 2018, we had outstanding \$230.0 million in aggregate principal amount of 3.250% convertible senior notes due 2023.

We expect to continue to incur net losses over at least the next several years due to significant expenditures relating to our continuing drug discovery efforts, preclinical and clinical development of our current product candidates, commercialization costs relating to VIBATIV and pre-commercialization costs and, if revefenacin is approved, commercialization costs relating to revefenacin. 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 expect the clinical development of our key development programs will require significant investment in order to continue to advance in clinical development. In addition, we expect to invest strategically in our research efforts to continue to grow our development pipeline. In the past, we have received a number of significant payments from collaboration agreements and other significant transactions. In the future, we expect to receive revenues from product sales and potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes. In addition, we recently began recognizing investment income arising from our economic interest in royalties payable by GSK to TRC. Our current business plan is subject to significant uncertainties and risks as a result of, among other factors, clinical program outcomes, whether, when and on what terms we are able to enter into new collaboration arrangements, expenses being higher than anticipated, the sales levels of VIBATIV, unplanned expenses, cash receipts being lower than anticipated, and the need to satisfy contingent liabilities, including litigation matters and indemnification obligations.

*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 from the issuance date of these condensed consolidated financial statements 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. However, future financing may not be available in amounts or on terms acceptable to us, if at all.

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:

| <b>(In thousands)</b>                               | <b>Three Months Ended<br/>March 31,</b> |             | <b>Change</b> |
|---|---|-------------|---------------|
|   | <b>2018</b>                             | <b>2017</b> |               |
| Net cash provided by (used in) operating activities | \$ 49,825                               | \$ (50,026) | \$ 99,851     |
| Net cash (used in) investing activities             | (11,294)                                | (123,522)   | 112,228       |
| Net cash (used in) financing activities             | (1,680)                                 | (1,216)     | (464)         |

*Cash flows provided by (used in) operating activities*

Net cash provided by operating activities increased by \$99.9 million primarily driven by receipt of \$100.0 million upfront payment from our collaborative arrangement from Janssen. For the three months ended March 31, 2018, \$49.8 million provided by operating activities consisted primarily of net loss of \$65.1 million, adjusted for non-cash items such as \$14.0 million for share-based compensation expense, and \$100.9 million of net cash inflow related to changes in operating assets and liabilities for the three months ended March 31, 2018.

Net cash used in operating activities was \$50.0 million for the three months ended March 31, 2017, consisting primarily of net loss of \$65.3 million, adjusted for non-cash items such as \$10.3 million for share-based compensation expense and \$3.9 million of net cash inflow related to changes in operating assets and liabilities for the three months ended March 31, 2017.

*Cash flows (used in) investing activities*

Net cash used in investing activities was \$11.3 million for the three months ended March 31, 2018, consisting of net cash outflows resulting from the purchases and maturities of marketable securities of \$8.5 million and \$2.8 million in cash outflow related to the acquisition of property and equipment.

Net cash used in investing activities was \$123.5 million for the three months ended March 31, 2017, consisting primarily of net cash outflows resulting from the purchases and maturities of marketable securities of \$122.9 million.

*Cash flows (used in) financing activities*

Net cash used in financing activities was \$1.7 million for the three months ended March 31, 2018, primarily consisting of the repurchase of shares to satisfy tax withholding obligations.

Net cash used in financing activities was \$1.2 million for the three months ended March 31, 2017, consisting of net cash outflows of \$4.0 million from the sale of shares to satisfy tax withholding obligations which was partially offset by the proceeds from employee option exercises of \$2.8 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 March 31, 2018.

In 2016, we granted long-term retention and incentive restricted share awards (“RSAs”) and restricted share units (“RSUs”) to members of senior management and long-term retention and incentive cash bonus awards to certain employees. The vesting and payout of such awards is dependent on the Company meeting its critical operating goals and objectives during a five-year period from 2016 to December 31, 2020. These goals are strategically important for the Company, and we believe the goals, if achieved, will increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment, and they are broken into three separate tranches. The maximum potential expense associated with all three tranches of this program is \$35.5 million related to share-based compensation expense and \$52.9 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. The maximum potential total expense associated with the first and second tranche of the program is \$19.8 million in share-based compensation expense and \$31.8 million in cash bonus expense. We have determined that achievement of the requisite performance conditions for the first and second tranches are probable due to achievement of certain performance conditions and multiple advancements of programs within our development pipeline and, as a result, we have recognized \$2.0 million in share-based compensation expense and \$3.3 million in cash bonus expense for the three months ended March 31, 2018. We determined that the remaining third tranche was not probable of vesting and, as a result, no compensation expense related to this tranche has been recognized.

### ***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, 2017, filed with the SEC on February 28, 2018.

### ***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, 2017, filed with the SEC on February 28, 2018.

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

Our market risks as of March 31, 2018 have not changed materially from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 28, 2018.

## **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 March 31, 2018, 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***

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 first quarter of the year ending December 31, 2018 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 Annual Report on Form 10-K 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., 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 three months ended March 31, 2018 and the years ended December 31, 2017 and 2016, we recognized losses of \$65.1 million, \$285.4 million and \$190.7 million, respectively, which are reflected in the Shareholders’ Equity on our consolidated balance sheets. We reflect cumulative net loss incurred after June 2, 2014, the effective date of our spin-off from Innoviva, Inc. (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) and, in anticipation of potential approval, revefenacin. In particular, to the extent we advance our product candidates into and through additional clinical studies, and particularly if we do so without a partner, we will incur substantial expenses. For example, in August 2017, we announced our decision to accelerate funding associated with the next phase of development of our intestinally restricted pan-Janus kinase (“JAK”) inhibitor program. We are also making additional investments in revefenacin in anticipation of potential approval. We incur all of the costs and expenses associated with the commercialization of VIBATIV in the US, including the maintenance of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, a medical affairs presence, manufacturing and third-party vendor logistics and consultant support, and post-marketing studies. Our commitment of resources to the continued development of our existing product candidates, our discovery programs, revefenacin and VIBATIV 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 (i) revenues from sales of VIBATIV, our only approved medicine, (ii) our economic interest in royalties from net sales of Trelegy paid to TRC, and (iii) potential payments under collaboration agreements, we do not expect to generate revenues in the immediate 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 the 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.

***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, new requirements for conducting future 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 US Food and Drug Administration (“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.

Any adverse developments or results or perceived adverse developments or results with respect to our clinical programs including, without limitation, any delays in development in our programs, any halting of development in our programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities with respect to our programs, or any indication from clinical or non-clinical studies that the compounds in our programs are not safe or efficacious, could have a material adverse effect on our business and cause the price of our securities to fall.

***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 US. We will not obtain this approval for a product candidate unless and until the FDA approves an 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, the FDA has additional standards for approval of new drugs, including recommended advisory committee meetings for certain 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 the use and/or distribution 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 or other regulatory authorities' 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.

***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. However, our current operating plans or financial forecasts occasionally change. For example, in 2016, our actual operating loss exceeded our anticipated operating loss, primarily because of accelerated enrollment in TOUR, increased funding for the development of our JAK inhibitors and increased investment in our neprilysin ("NEP") inhibitor program. In August 2017, we announced an increase in our anticipated operating loss for 2017, primarily driven by our decision to accelerate funding associated with the next phase of development of our JAK inhibitor program. 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.

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 and any additional approved products and to prepare for potential product approvals;

- support our independent sales and marketing organization and medical affairs team;
- support our additional investments in revefenacin in anticipation of potential approval;
- progress any additional product candidates into later-stage development without funding from a collaboration partner;
- 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 additional debt, including 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. The terms of our existing 3.250% convertible senior notes due 2023 (“Notes”) do not restrict our ability to issue additional debt. 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, since our Spin-Off in June 2014, we have raised an aggregate of \$583.9 million through the sale of approximately 17.5 million shares and \$230.0 million aggregate principal amount of Notes in a combination of private sale, public offerings and at-the-market sales. 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 any additional debt securities we may issue in the future 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 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 Alfasigma S.p.A. (“Alfasigma”) (formerly Alfa Wassermann S.p.A.) for velusetrag, our internally discovered 5-HT4 agonist for the treatment of gastromotility disorders, under which we will transfer to Alfasigma global rights for velusetrag. 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. 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 is responsible for worldwide development and commercialization of TD-8954. In early February 2018, we announced a global co-development and commercialization agreement with Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn’s disease. In connection with these agreements, these parties have certain rights regarding the use of patents and technology with respect to the compounds in our development programs, including development and marketing rights.

We also have commercialization agreements with various partners for the commercialization of VIBATIV outside of the US, 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 EU to Theravance Biopharma and, since we do not intend to commercialize VIBATIV in the EU without a partner and have been unable to secure another partner to commercialize VIBATIV in the EU, in early 2018 we withdrew VIBATIV’s EU marketing authorization.

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 EU 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.

***We do not control TRC and, in particular, have no control over the GSK-Partnered Respiratory Programs or access to non-public information regarding the development of 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”), which agreements govern Innoviva’s and GSK’s respective interests in the GSK-Partnered Respiratory Programs. Our equity interest covers various drug programs including all Trelegy Ellipta (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA® inhaler, previously referred to as the Closed Triple) products 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 work GSK and Innoviva are undertaking with respect to 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 there are any adverse developments or perceived adverse developments with respect to the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including Trelegy Ellipta and the MABA program, our business will be harmed, and the price of our securities could fall.***

We have no access to confidential information regarding the development progress of, or plans for, the GSK-Partnered Respiratory Programs, including Trelegy Ellipta 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 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 of any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- the 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;

- any safety, efficacy or other concerns regarding any of the GSK-Partnered Respiratory Programs in which we have a substantial economic interest;
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs;
- the emergence of new closed triple or other alternative therapies or any developments regarding these potentially competitive therapies, comparative price or efficacy of such potentially competitive therapies;
- disappointing or lower than expected sales of Trelegy Ellipta; or
- disputes between GSK and Innoviva.

***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 March 31, 2018, GSK beneficially owned approximately 17.6% of our outstanding ordinary shares. GSK is also a strategic partner to Innoviva with rights and obligations under the GSK Agreements, which include the strategic alliance agreement and the collaboration agreement assigned to TRC, that may cause GSK's interests to differ from our interests and those of our other shareholders. In particular, following the approval of Trelegy Ellipta in the US and if a MABA/ICS is approved in either the US or the EU, GSK's diligent efforts obligations under the GSK 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 Agreements. 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 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 Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK 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. Before 2018, the actions GSK could have taken to acquire us were limited under our governance agreement with GSK (the "Governance Agreement"), but this agreement expired 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 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 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 (the "Master Agreement"), or otherwise violating its legal rights. While we believe our operations fully comply with the GSK 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 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.

***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 or completed. If our ongoing clinical studies for our current product candidates, such as the clinical studies for our JAK inhibitor program or TD-9855 in patients with nOH, are substantially delayed or suggest that our product candidate may not be efficacious or well tolerated, we could choose to cease development 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.

***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 and enforce patent and/or other proprietary protection for our medicines and technologies;
- conduct effective clinical trials and 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, linezolid and daptomycin, 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. If approved as the first once-daily nebulized LAMA, revefenacin would be expected to compete predominantly with short-acting nebulized bronchodilators used three to four times per day and the nebulized LAMA Lonhala™ Magnair™ (SUN-101/eFlow®) used twice per day. 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.

***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 Janssen for TD-1473 and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease, Mylan for the development and commercialization of a nebulized formulation of revefenacin (TD-4208), our LAMA compound, Alfasigma 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. 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 to commercialize the product candidates in our 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, though we have been unable to reach an agreement with a replacement partner to commercialize VIBATIV in the EU and have withdrawn the marketing authorization for VIBATIV in the EU, which will make reaching any such an agreement with respect to the EU more difficult. 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.

Collaborations with third parties regarding our 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, may cause us not to continue commercialization of our authorized products and could cause the price of our securities to fall.

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

We depend on independent clinical investigators, contract research and manufacturing 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, laboratory and manufacturing practices (“GXP”) 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 and practices 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 GXPs 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 GXPs (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 cause the price of our securities to 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 Active Pharmaceutical Ingredient (“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 current Good Manufacturing Practice (“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 higher 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 US, there may be difficulties in importing our APIs and drug products or their components into the US as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.



***Servicing our Notes requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Additionally, holders may require us to repurchase our Notes under certain circumstances, and we may not have sufficient cash to do so.***

Our ability to make interest or principal payments when due or to refinance the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations sufficient to satisfy our obligations under the Notes and any future indebtedness we may incur and to make necessary capital expenditures. We may be required to adopt one or more alternatives, such as reducing or delaying investments or capital expenditures, selling assets, refinancing or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Notes or future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities on desirable terms or at all, which could result in a default on the Notes or future indebtedness.

Additionally, holders of the Notes may have the right to require us to repurchase the Notes upon the occurrence of a “fundamental change” such as a change of control of our Company or the termination of trading of our ordinary shares, as defined in the indenture, as amended, governing the Notes. We may not have sufficient funds to repurchase the Notes in cash or have the ability to arrange necessary financing on acceptable terms. Our failure to repurchase the Notes when required would result in an event of default with respect to the Notes. Any acceleration of the repayment of the Notes or future indebtedness after any applicable notice or grace periods could have a material adverse effect on our business, results of operations and financial condition.

***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, including cloud-based and hosted applications, data and services, 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, we may incur legal expenses to protect our confidential information, 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. In 2017, we filed a lawsuit against a former employee we have reason to believe misappropriated our confidential, proprietary and trade secret information. Moreover, there can be no assurance that such security measures will prevent service interruptions or security breaches that could adversely affect our business.

***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 US 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.

***Global health and economic, political and social conditions may harm our ability to do business, increase our costs and negatively affect our stock price.***

Worldwide economic conditions remain uncertain due to the decision by the United Kingdom to initiate the formal procedure of withdrawal from the EU (often referred to as “Brexit”), current economic challenges in Asia and other disruptions to global and regional economies and markets.

Brexit has created significant uncertainty about the future relationship between the United Kingdom and the EU, including with respect to the laws and regulations that will apply as the United Kingdom determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the United Kingdom’s withdrawal could bear significant complexity and risks. In addition, the exact terms of the United Kingdom’s withdrawal and the laws and regulations that will apply after the United Kingdom withdraws from the EU would affect manufacturing sites that hold an EU manufacturing authorization issued by the United Kingdom competent authorities. The referendum has also given rise to calls for the governments of other EU Member States to consider withdrawal from the EU.

Our operations also depend upon favorable trade relations between the US and those foreign countries in which our materials suppliers have operations. A protectionist trade environment in either the US or those foreign countries in which we do business, such as a change in the current tariff structures, export compliance or other trade policies, may materially and adversely affect our operations. External factors, such as potential terrorist attacks, acts of war, geopolitical and social turmoil or epidemics and other similar outbreaks in many parts of the world, could also prevent or hinder our ability to do business, increase our costs and negatively affect our stock price. These geopolitical, social and economic conditions could harm our business.

***Our US 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 US 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 and costly 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.



***VIBATIV has not been broadly accepted by physicians, patients, third-party payors, or the medical community in general, and we may never generate significant revenue or profits from VIBATIV.***

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), linezolid and daptomycin, all 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. To date, VIBATIV has not been broadly accepted by physicians, patients, third-party payors, or the medical community in general, we believe primarily due to the availability of low cost generic antibiotic products such as vancomycin and daptomycin. Although we continue to view VIBATIV as an important medicine to treat serious infections in very sick patients and we intend to continue to support the product, given the challenges we have faced commercializing VIBATIV in a highly competitive environment against generic drugs, we have reduced and are closely managing our overall spending related to the product. In the future, if we are unable to demonstrate to physicians, patients, hospitals, healthcare systems third-party payors and the medical community in general 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 or profits from VIBATIV.

***We are responsible for marketing, sales and distribution of VIBATIV in the US and we may bear similar costs with respect to additional products in the future, including revefenacin if approved, which subjects us to certain risks.***

We currently maintain a limited VIBATIV sales force in the US and plan to add US revefenacin sales and marketing personnel throughout 2018 to support our co-promotion obligations under our agreement with Mylan should revefenacin be approved. The risks of continuing to support VIBATIV in the US without a partner and fulfilling our US co-promotion obligations to Mylan if revefenacin is approved include:

- costs and expenses associated with creating and maintaining 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, revefenacin or any future products for several years;
- our ability to retain effective sales and marketing personnel and medical science liaisons in the US;
- the ability of our sales and marketing personnel to obtain access to and educate adequate numbers of physicians about prescribing VIBATIV and, if approved, revefenacin, or any future products, in appropriate clinical situations; and
- 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.

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, or any future products such as revefenacin (if approved), in appropriate clinical situations, we will have difficulty commercializing these products, which would adversely affect our business and financial condition and the price of our securities could fall.

***We rely on a single manufacturer for the 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 cGMP compliance, we may not be able to 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. We currently have sufficient quantities of VIBATIV drug product on hand to meet our anticipated needs until approximately the fourth quarter of 2019. This supply was manufactured by Pfizer, our single source manufacturer for VIBATIV, at its McPherson, Kansas facility. Pfizer received an FDA warning letter relating to a 2016 inspection of this facility and was notified that the FDA has upgraded the status of the facility to Voluntary Action Indicated (VAI) in early 2018. None of the lots cited in the warning letter were manufactured VIBATIV drug product. We are also planning to have additional VIBATIV drug product manufactured for us at this facility in 2018. 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 could adversely affect the commercialization of VIBATIV and our obligations to our partners. 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. If either of these were to occur, our business would be harmed.

Our current agreement with Pfizer to supply VIBATIV drug product was entered into May 2012. In June 2013, the FDA approved Pfizer as a VIBATIV drug product manufacturer. On September 29, 2016, we amended our agreement with Pfizer to extend the term of the agreement to December 31, 2020. If our supply relationship with Pfizer terminates for any reason, 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 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 the FDA, including substantiation of promotional claims, disclosure of risks and safety information, and the use of themes and imagery in advertising and promotional materials. As with all companies selling and marketing products regulated by the FDA in the US, we are prohibited from promoting any uses of VIBATIV that are outside the scope of those uses that have been expressly approved by the FDA as safe and effective on the VIBATIV label.

The US 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, patients receive a medication guide with each course of antibiotic use in connection with the approved labeling for VIBATIV. Further, the VIBATIV labeling for hospital-acquired and ventilator associated bacterial pneumonia (“HABP/VABP”) 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.

Under the Pediatric Research Equity Act (PREA), the FDA also requires that we conduct two pediatric pharmacokinetic studies, one Phase 3 randomized, comparator-controlled study in pediatric patients with Gram-positive infections, as well as a study gathering data regarding the treatment of cSSSI in pediatric patients. If we are unable to meet the applicable deadlines for any of these studies, FDA may issue us a non-compliance letter, to which will be required to respond within 45 days. FDA's non-compliance letter and our response will be posted publicly on the FDA website. If we

continue to be unable to meet our deadlines, FDA may deem VIBATIV to be misbranded and, on that basis, VIBATIV could be subject to injunction proceedings or seizure by FDA.

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 US 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 US 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.

Failure to satisfy required post-approval requirements and/or commitments may have implications for a product's approval and may carry civil monetary penalties. 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 US 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, and which may cause the price of our securities to fall.

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

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 2027 that are listed in 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.

For additional 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 current or future markets.*”

***We may be treated as a US corporation for US federal income tax purposes.***

For US 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-US 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 US corporation for US 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 US will be treated as a US corporation for US federal tax purposes if (i) the foreign corporation directly or indirectly acquires substantially all of the properties held directly or indirectly by a US corporation, (ii) the former shareholders of the acquired US 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 US 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 US 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 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 US 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 US corporation.

If it were determined that we should be treated as a US corporation for US federal income tax purposes, we could be liable for substantial additional US federal income tax on our post-Spin-Off taxable income. In addition, though we have no current plans to pay any dividends, payments of any dividends to non-US holders may be subject to US 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, the 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. We are aware that Ireland is expected to implement certain tax law changes to comply with the European Union Anti-Tax Avoidance Directives. These changes will include the first ever Irish controlled foreign company rules which are expected to be effective on January 1, 2019. It is also expected that Ireland will implement certain transfer pricing rule changes, most likely with effect from 2020. Proposed statutory language has not yet been provided for either set of rules, and as a result, we have not yet been able to determine the impact, if any, of such future legislation on our 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.

***We were a passive foreign investment company, or “PFIC,” for 2014, but we were not a PFIC from 2015 through 2017, and we do not expect to be a PFIC for the foreseeable future.***

For US federal income tax purposes, we generally would be classified as a PFIC for any taxable year if either (i) 75% or more of our gross income (including gross income of certain 25% or more owned corporate subsidiaries) is “passive income” (as defined for such purposes) or (ii) the average percentage of our assets (including the assets of certain 25% or more owned corporate subsidiaries) that produce passive income or that are held for the production of passive income is at least 50%. In addition, whether our Company will be a PFIC for any taxable year depends on our assets and income over the course of each such taxable year and, as a result, cannot be predicted with certainty until after the end of the year.

Based upon our assets and income during the course of 2014, we believe that our Company and one of our Company’s wholly-owned subsidiaries, Theravance Biopharma R&D, Inc. was a PFIC for 2014. Based upon our assets and income from 2015 through 2017, we do not believe that our Company is a PFIC during these three years. We do not expect to be a PFIC for the foreseeable future based on our current business plans and current business model. For any taxable year (or portion thereof) in which our Company is a PFIC that is included in the holding period of a US holder, the US holder is generally subject to additional US federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma R&D, Inc. US holders of our ordinary shares may have filed an election with respect to Company shares held at any time during 2014 to be treated as owning an interest in a “qualified electing fund” (“QEF”) or to “mark to market” their ordinary shares to avoid the otherwise applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. A foreign corporation will not be treated as a QEF for any taxable year in which such foreign corporation is not treated as a PFIC. QEF and mark to market elections generally apply to the taxable year for which the election is made and all subsequent taxable years unless the election is revoked with consent of the Secretary of Treasury. US holders of our ordinary shares should consult their tax advisers regarding the tax reporting implications with respect to any QEF and mark to market elections made with respect to our Company and with respect to their indirect interests in Theravance Biopharma R&D, Inc.

***If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.***

If we are unable to 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 require annual management assessments of 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. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting annually. If our independent registered public accounting firm is unable to attest to the effectiveness of our internal control over financial reporting, investor confidence in our reported results will be harmed and the price of our securities may fall. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

***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 the Master

Agreement which, among other things, requires GSK's consent to make any changes to (A) a 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 expired on 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 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.

***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 most of our officers and 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 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, a Transition Services Agreement, an Employee Matters Agreement, a Tax Matters Agreement, and a 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 current or future markets.***

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 March 31, 2018, we owned 466 issued United States patents and 1,979 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 misappropriated, disclosed or used for unauthorized purposes 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.

***Litigation to protect or defend our intellectual property 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, prevent the unauthorized use or disclosure of our trade secrets and confidential information, or defend the validity of our patents. For example, in 2017 we filed a lawsuit against a former employee we have reason to believe misappropriated and retains certain of our confidential, proprietary and trade secret information. Prosecution of claims to enforce or defend our rights against others involve substantial litigation expenses and divert substantial employee resources from our business but may not result in adequate remedy to us or sufficiently mitigate the harm to our business caused by any intellectual property infringement, unauthorized access, use or disclosure of trade secrets. 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 and other 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. 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 HAP/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 HAP/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. We also face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials. In addition, changes in laws outside the US are expanding our potential liability for injuries that occur during clinical trials. Product liability claims could harm our reputation, regardless of the merit or ultimate success of the claim, which may adversely affect our and our partners' ability to commercialize our products and cause the price of our securities to fall. 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.

We may also be required to prosecute or defend general commercial, intellectual property, securities and other lawsuits. Litigation typically involves substantial expenses and diverts substantial employee resources from our business. The cost of defending any product liability litigation or engaging in any other legal proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of the litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and achieve our business goals.

***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 US, 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 and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that 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 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.

These obligations will be further substantiated with the entry into force of the General Data Protection Regulation on May 25 2018. 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. When processing personal data of subjects in the EU, we have to comply with the applicable data protection laws. In particular, as we rely on services providers processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the US, a decision of the European Court of Justice in the *Schrems* case (Case C-362/14 Maximilian 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 US. 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-US “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. US companies have been able to certify to the US Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, an Irish privacy advocacy group brought an action for annulment of the EC decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 and Case T-738/16 are still pending before the European Court of Justice. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive. 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 US (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. The EU General Data Protection Regulation entered into force on May 24, 2016 and will apply from May 25, 2018, repealing the current EU Data Protection Directive. 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. Individuals, including patients and persons within our partners, may have contractual or regulatory rights that limit our ability to use or disclose related information. We may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

***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 new presidential administrations, 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 and may in the future be 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 enactments.

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, including 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 program, fraud and abuse and enforcement. These changes impact existing government healthcare programs and are resulting 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, 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, certain legislative changes to and regulatory changes under the Health Reform Act have occurred in the 115th US Congress and under the Trump Administration. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional legislative changes to and regulatory changes under the Health Reform Act remain possible, but the nature and extent of such potential additional changes are uncertain at this time. 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.

In addition, there have been proposals to impose federal rebates on Medicare Part D drugs, requiring federally-mandated rebates on all drugs dispensed to Medicare Part D enrollees or on only those drugs dispensed to certain groups of lower income beneficiaries. If any of these proposals are adopted they could result in Theravance owing additional rebates, which could have a negative impact on revenues from sales of our products.

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, if approved, 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 US 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 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.

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 the final 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 continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulations.

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 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"), the federal agency that administers the 340B program, recently updated the agreement with participating manufacturers. The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program. On January 5, 2017, HRSA issued a final regulation regarding the calculation of 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. The effective date of the regulation has been delayed until July 1, 2018. Implementation of this final rule and the issuance of any other 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 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.

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 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 \$181,071 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 \$13,066 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 \$18,107 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 Department of Veterans Affairs (“VA”), Department of Defense (“DoD”), Public Health Service, and Coast Guard (the “Big Four agencies”) and certain federal grantees, we are required to participate in the 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 to the Big Four agencies that is no higher than the Federal Ceiling Price (“FCP”), which is a price calculated pursuant to a statutory formula. The FCP is derived from 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 approximately \$200,000 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 to DoD on utilization of innovator products that are dispensed through DoD’s Tricare network pharmacies to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP for the calendar year that the product was dispensed. 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.

***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 approximately \$11,000 to \$22,000 per false claim or statement for violations occurring after November 2, 2015. 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, and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes.
- Similar restrictions are imposed on the promotion and marketing of medicinal products in the EU Member States 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 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 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. In addition, as further described below under the risk factor entitled “—*Concentration of ownership will limit your ability to influence corporate matters,*” a number of shareholders hold large concentrations of our shares which, if sold within a relatively short timeframe, could cause the price of our shares to drop significantly.

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. 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 our pending NDA for revefenacin;
- any adverse developments or results or perceived adverse developments or results with respect to our key clinical programs for example, our JAK inhibitor program or TD-9855 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 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, any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious or lower than expected sales of Trelegy Ellipta;
- 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 our relationship with Innoviva, or 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;



- 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;
- possible impairment charges on non-marketable equity securities;
- economic and other external factors beyond our control, such as fluctuations in interest rates;
- 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;
- the sale of large concentrations 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 March 31, 2018 GSK beneficially owned approximately 17.6% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 7.1% of our outstanding ordinary shares. Based on our review of publicly available filings, as of March 31, 2018 our three largest shareholders other than GSK collectively owned approximately 53.1% of our outstanding 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 (2016 Revision) 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 US. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the US, 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) our 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 US 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.

***We do not anticipate paying any cash dividends on our capital shares in the foreseeable future; as a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our capital shares. We do not anticipate paying any cash dividends on our capital shares in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our ordinary shares. As a result, capital appreciation, if any, of our ordinary shares will be your sole source of gain for the foreseeable future.

**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         | <a href="#">Amended and Restated Memorandum and Articles of Association</a>   |                | 10-12B                    | April 30, 2014              |
| 10.1*       | <a href="#">License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Janssen Biotech, Inc. dated as of February 5, 2018</a>  | X              |                           |                             |
| 31.1        | <a href="#">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</a>  | X              |                           |                             |
| 31.2        | <a href="#">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</a>  | X              |                           |                             |
| 32(1)       | <a href="#">Certifications Pursuant to 18 U.S.C. Section 1350</a>   | X              |                           |                             |
| 101         | Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2018, 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 are being furnished to accompany the Report pursuant to 18 U.S.C. Section 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: May 9, 2018

*/s/ Rick E Winningham*

\_\_\_\_\_  
**Rick E Winningham**

Chairman of the Board and Chief Executive Officer  
(Principal Executive Officer)

Date: May 9, 2018

*/s/ Renee D. Gala*

\_\_\_\_\_  
**Renee D. Gala**

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

**LICENSE AND COLLABORATION AGREEMENT**

by and between

THERAVANCE BIOPHARMA IRELAND LIMITED,

and

JANSSEN BIOTECH, INC.

Dated as of February 5, 2018

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## LICENSE AND COLLABORATION AGREEMENT

This **LICENSE AND COLLABORATION AGREEMENT** (the “**Agreement**”) is entered into as of February 5, 2018 (the “**Effective Date**”) by and between **THERAVANCE BIOPHARMA IRELAND LIMITED**, a corporation organized under the laws of Ireland, with its principle place of business at Connaught House, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland (“**Theravance**”), and **JANSSEN BIOTECH, INC.**, a Pennsylvania corporation, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania, 19044, United States (“**Janssen**”). Theravance and Janssen are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

**WHEREAS**, Janssen is a pharmaceutical company with expertise in the development, marketing, and commercialization of pharmaceutical products;

**WHEREAS**, Theravance possesses certain intellectual property, materials and expertise related to certain Compounds (as defined below); and

**WHEREAS**, the Parties desire to establish a collaboration regarding such Compounds and certain products incorporating such Compounds all in accordance with the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

**1.1** “Additional Combination Net Sales Language” means the following sentence: “In the event a Product is sold as part of a Combination Product in a country, the Net Sales with respect to the Combination Product in such country (for all financial terms pursuant to this Agreement) shall be determined by multiplying Net Sales of such Combination Product by the fraction  $A/(A+B)$  where A is the Average Net Selling Price of the Product component contained in the Combination Product, if sold separately or subject to reasonable estimation, and B is the sum of the Average Net Selling Prices of any other product components included in the Combination Product, if sold separately or subject to reasonable estimation.”

**1.2** “Additional Compound” means a JAK Inhibitor, other than (a) the Compounds described in Section 1.25(a)-(c) and (b) the Solar Compounds.

**1.3** “Affiliate” means any business entity which now or hereafter controls, is controlled by, or is under common control with a Party, for so long as such control exists. A business entity shall be deemed in control of another business entity if it directly or indirectly owns, or directly or indirectly controls more than fifty percent (50%) of the voting stock, profit interests, or other ownership interests of the other entity, or has the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the other entity.

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**1.4** “Antitrust Law” means any statutes, laws, ordinances, rules, orders or regulations of, or issued by, any governmental authority that are designed or intended to prohibit, restrict or regulate actions that may have the purpose or effect of creating a monopoly, lessening competition or restraining trade, including the HSR Act.

**1.5** “Applicable Rate” means the average one-month London Inter-Bank Offering Rate (LIBOR) as reported on the day a payment was due in *The Wall Street Journal* (U.S. Internet version at [www.wsj.com](http://www.wsj.com) under the “Market Data” tab), plus [\*\*\*] percent ([\*\*\*]%) annually.

**1.6** “Average Net Selling Price” means, on a product-by-product basis, for a given product, Calendar Year and reference jurisdiction, expressed in the applicable local currency, the aggregate Net Sales, divided by the number of units of such product for which revenue has been recognized by the Parties.

**1.7** “Business Day” means a day other than Saturday, Sunday or any day that banks in Dublin, Ireland or New York City, U.S. are required or permitted to be closed.

**1.8** “Calendar Quarter” means a financial quarter based on the J&J Universal Calendar for that year (a copy of which is attached hereto as Exhibit L) and is used by Janssen and its Affiliates for internal and external reporting purposes; provided, however, that the first Calendar Quarter for the first Calendar Year extends from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter extends from the first day of such Calendar Quarter until the effective date of the termination or expiration of the Agreement.

**1.9** “Calendar Year” means a year based on the J&J Universal Calendar for that year. The last Calendar Year of the Term begins on the first day of the J&J Universal Calendar for the year during which termination or expiration of the Agreement will occur, and the last day of such Calendar Year will be the effective date of such termination or expiration.

**1.10** “Change of Control” of a Party means (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer, directly or indirectly, to a Third Party of all or substantially all of such Party’s assets to which the subject matter of this Agreement relates, except in connection with the issuance of equity securities for financing purposes or to change the domicile of a Party (in each case (a) – (c), inclusive, such Third Party, the “Acquiring Entity”).

**1.11** “Clinical Development Plan” means the Parties’ written plan for the clinical Development of the Initial Product during the Development Term, as amended from time to time, which shall include the budget and timelines described in Article 4. The initial Clinical Development Plan is attached hereto as Exhibit E. For clarity, the Clinical Development Plan may be expanded to include additional Compounds or Products as agreed by the Parties in accordance with Section 4.2(b).

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**1.12** “Clinical Trial” means any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, or any post-approval human clinical trial, as applicable.

**1.13** “CMC” means the chemistry, manufacturing and controls of the Product, as specified by the FDA, or other applicable Regulatory Authorities.

**1.14** “CMC Development” means (a) Development activities related to the composition, manufacture and specification of Compound API and Product intended to assure the proper identification, quality, purity and strength of the Product, including: test method development and stability testing, process development, Compound API process development, process validation, process scale-up, formulation development, packaging development, quality assurance and quality control development; and (b) preparation of CMC Regulatory Materials.

**1.15** “CMC Development Plan” means the Parties’ written plan for CMC Development and Manufacturing of the Initial Compound and Initial Product during the Development Term, as amended from time to time, which shall include the budget and timelines described in Article 4. The initial CMC Development Plan is attached hereto as Exhibit F. For clarity, the CMC Development Plan may be expanded to include additional Compounds or Products, if the Clinical Development Plan is so expanded upon mutual agreement of the Parties in accordance with Section 4.2(b).

**1.16** “Collaboration” means the Parties’ activities in connection with Development of the Compounds and Products conducted pursuant to this Agreement during the Development Term.

**1.17** “Collaboration Activities” means, collectively, the Phase 2 Activities, Phase 3 Activities and Collaboration CMC Activities, or other Development activities conducted by or on behalf of the Parties pursuant to the Collaboration Plans.

**1.18** “Collaboration CMC Activities” means, collectively, the CMC Development activities set forth in the CMC Development Plan.

**1.19** “Collaboration CMC Costs” means (a) with respect to the Manufacturing of clinical supplies of Compound API or Product for the Phase 3 Activities pursuant to the CMC Development Plan, the Manufacturing costs incurred by either Party or any of its Affiliates in performing such activities and (b) with respect to all other Collaboration CMC Activities, the reasonable, attributable and required internal costs and reasonable, documented Third Party costs incurred by a Party or its Affiliates in performing such activities, in each case in accordance with the budget set forth in such CMC Development Plan.

**1.20** “Collaboration Know-How” means Know-How developed by the Parties pursuant to the Collaboration Plans.

**1.21** “Combination Product” means a Product that contains one or more active agents in addition to a Compound.

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**1.22** “Commercial Budget” means the budget included as part of each Commercialization Plan, as updated annually for each Calendar Year, setting forth the anticipated spending required for executing the Commercialization Plan.

**1.23** “Commercialization” means, with respect to a Product, the marketing, promotion, importing, sale and/or distribution of such Product in the Territory. Commercialization shall include commercial activities conducted in preparation for Product launch. “Commercialize” has a correlative meaning.

**1.24** “Commercially Reasonable Efforts” means, with respect to each Party’s obligations under this Agreement, [\*\*\*] and other factors that may affect the Development, Marketing Approval, manufacturing or Commercialization of a product, including (as applicable): [\*\*\*].

**1.25** “Compound” means each of (a) TD-1473; (b) TD-3504; (c) any compound disclosed by the TD-1473 and TD-3504 Patent Families; (d) any Additional Compound proposed by Theravance at its sole discretion and accepted by Janssen pursuant to Section 2.5(a), and (e) any Solar Compound; together, in each case, with all prodrugs, metabolites, salts, esters, hydrates, solvates, isomers, enantiomers, free acid forms, free base forms, crystalline forms, co-crystalline forms, amorphous forms, racemates, polymorphs, chelates, stereoisomers, tautomers or optically active forms thereof. The Compound listed in (a) above may be referred to herein as the “Initial Compound.” The Lunar Compounds or Solar Compounds may be excluded from the definition of Compound in accordance with Section 2.5(b)(iii-iv).

**1.26** “Compound API” means the active pharmaceutical ingredient for a Compound.

**1.27** “Confidential Information” of a Party means any and all non-public and proprietary data, results, technology, business or financial information or information of any type whatsoever, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical and clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures of such Party, in each case that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. In addition, all Information disclosed by Theravance Biopharma US, Inc. (“TBUS”), an Affiliate of Theravance, pursuant to the Non-Disclosure Agreement between TBUS and Janssen Research & Development, LLC (“JRD”), an Affiliate of Janssen, dated September 8, 2017 (the “Confidentiality Agreement”) shall be deemed to be Theravance’s Confidential Information disclosed hereunder, and all Information disclosed by JRD pursuant to the Confidentiality Agreement shall be deemed to be Janssen’s Confidential Information disclosed hereunder.

**1.28** “Control” means, with respect to any material, Know-How, Data, or intellectual property right (including Patent Right), that a Party (a) owns (directly or through an Affiliate) or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Know-How, Data, or intellectual property right (including Patent Right) and, in each case (a) and (b), has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms

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of any then-existing agreement or other legally enforceable arrangement with any Third Party. Notwithstanding anything to the contrary in this Agreement, in the event of a Change of Control of a Party, (i) any subject matter owned or controlled by any Acquiring Entity (and not Controlled by such Party or its Affiliates) immediately prior to the effective date of such Change of Control and (ii) any subject matter independently developed or acquired by or on behalf of any Acquiring Entity without access to or use of any subject matter used or made available under this Agreement, in each case (i) and (ii) shall not be deemed to be Controlled by such Party or its Affiliates after the effective date of such Change of Control for purposes of this Agreement.

**1.29** “Cover” means, with respect to any subject matter, that the manufacturing, using, selling, or offering for sale of such subject matter would, but for a license granted in this Agreement, infringe a claim of a Patent Right in the country in which the activity occurs.

**1.30** “Covered Delivery” means, with respect to a Product, any method of delivery, other than any [\*\*\*].

**1.31** “Currency Hedge Rate” means the Johnson & Johnson currency hedge rate, which is the result of the effectively performed currency hedging at Johnson & Johnson for the upcoming Calendar Year and will be set up once per Calendar Year and will remain constant throughout such Calendar Year. The Johnson & Johnson currency hedge rate is calculated as a weighted average hedge rate of the outstanding external foreign currency forward hedge contracts of Johnson & Johnson with Third Party banks, all in accordance with its normal practices consistently applied for Janssen and its Affiliates.

**1.32** “Data” means all data and information used or developed to commence a Clinical Trial for a Product and included in the IND for such Clinical Trial, all data and information developed as a result of such Clinical Trial, and all data and information resulting from CMC work conducted in furtherance of the development of a Product (including stability data), as well as all data and information arising from the Collaboration (including pharmacological, biological, chemical, biochemical and clinical test data and data resulting from non-clinical studies).

**1.33** “Detail” means one (1) Primary Call or two (2) Secondary Calls. E-details, sample drops (if applicable) and reminder details shall not constitute a Detail. With regard to presentations made at conventions or similar gatherings, Details shall include that number of Details represented by the members of the target audience in attendance. For the avoidance of doubt, Details may occur in group situations if the definition of a Detail is met.

**1.34** “Detail Costs” means, with respect to any period, the Detail Rate multiplied by the number of Details by a Party during such period.

**1.35** “Detail Rate” means a mutually agreed upon cost per Detail, which shall, prior to Janssen’s provision of the Commercialization Plan, be agreed between the Parties acting reasonably and in good faith and commensurate with the fair market value of such activities.

**1.36** “Develop” or “Development” means, with respect to a Product, all activities that relate to the development of such Product, including (a) obtaining, maintaining or expanding

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Marketing Approvals for such Product, or (b) developing the ability to manufacture clinical and commercial quantities of such Product. Development includes: (i) the conduct of preclinical testing, toxicology, and clinical trials necessary to obtain Marketing Approval; (ii) manufacture of clinical trial materials; (iii) labeling, packaging, storage and distribution of clinical trial materials; (iv) preparation, submission, review, and development of Information for the purpose of submission to a Governmental Authority to obtain, maintain or expand Marketing Approvals for such Product; and (v) CMC Development.

**1.37** “Development Budget” means the budget included as part of the Collaboration Plans, setting forth the anticipated Development Costs associated with executing the Collaboration Plans, which overall budget shall incorporate the Phase 2 Budget, Phase 3 Development Budget, and CMC Budget.

**1.38** “Development Costs” means those Development FTE Costs and Out-of-Pocket Costs, in each case to the extent reasonably documented and actually incurred by or on behalf of a Party or any of its Affiliates in performing its obligations under and in accordance with the Collaboration Plans, including the associated budgets, that are specifically identifiable and directly attributable to Development of Products in the Field in the Territory.

**1.39** “Development FTE” means the contribution of time equivalent to one (1) year of a full-time employee qualified to perform the Development duties assigned to such employee under the Collaboration Plans, based on the assumption that one full-time employee devotes one thousand eight hundred (1,800) hours of work to his or her duties per year. Development FTEs may comprise one or more qualified employees or contractors or consultants of Theravance or its Affiliates or Janssen or its Affiliates, but shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

**1.40** “Development FTE Cost” means, with respect to any period, the Development FTE Rate multiplied by the number of Development FTEs expended by a Party during such period.

**1.41** “Development FTE Rate” means a rate of [\*\*\*] per Development FTE per Calendar Year (pro-rated for the period beginning on the Effective Date and ending on the last day of the first Calendar Year of the Term); *provided, however*, that [\*\*\*]. The Development FTE Costs are “fully burdened” and will cover employee salaries and overhead allocated to such employee’s work hereunder, including such facilities and equipment and other materials and services, including ordinary laboratory consumables procured from distributors of relevant products as they may use.

**1.42** “Development Term” means that portion of the Term beginning on the Effective Date and continuing, on a Product-by-Product basis, for so long as the Parties are conducting Development activities for such Product pursuant to this Agreement.

**1.43** “Diligent Efforts” means [\*\*\*].

**1.44** “Dollar” means a U.S. dollar, and “\$” shall be interpreted accordingly.

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1.45 “EMA” means the European Medicines Agency or any successor entity with comparable responsibilities.

1.46 “Executive Officer” means, with respect to Theravance, the Chief Executive Officer of its ultimate parent company, and with respect to Janssen, its Global Head of Research & Development or its Global Therapeutic Area Head, Immunology, or, in each case, a designee with senior decision-making authority.

1.47 “Exploit” or “Exploitation” means to research, Manufacture, import, export, use, have used, Develop, Commercialize, register, modify, enhance, improve or otherwise dispose of a Compound or Product.

1.48 “FD&C Act” means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.49 “FDA” means the U.S. Food and Drug Administration or any successor entity in the U.S. with comparable responsibilities.

1.50 “Field” means all human prophylactic, therapeutic and diagnostic uses.

1.51 “First Commercial Sale” means, with respect to a Product, the first arms-length commercial sale to a Third Party of such Product in a given regulatory jurisdiction after Marketing Approval has been obtained in such jurisdiction for such Product. Notwithstanding anything herein to the contrary, if the First Commercial Sale of a Product occurs in a country or jurisdiction, then Marketing Approval shall be deemed to have been received in such country or jurisdiction, regardless of whether any pricing and reimbursement approvals that are not legally required to launch such Product in such country or jurisdiction have been obtained. For avoidance of doubt, (i) sales for Clinical Trial purposes, early access or compassionate use programs, or similar uses or (ii) sales of a Product by and between a Party and its Affiliates, and applicable sublicensees, or between the Parties, shall not constitute a First Commercial Sale.

1.52 “FTE Costs” means “fully burdened” costs of the Parties’ employees qualified to perform the activities assigned to such employee under this Agreement and will cover employee salaries, bonus rate, and overhead allocated to such employee’s work hereunder.

1.53 “Fundamental Development Plan Change” means any of the following changes with respect to then-current Clinical Development Plan having last been approved by both Parties and that is not required by a Regulatory Authority: (a) addition or removal of any Clinical Trial to or from such Clinical Development Plan, (b) a material change to the timeline for conducting any Clinical Trial, (c) a material change to the primary endpoints of any Clinical Trial, (d) any material change to the number of subjects and enrollment criteria for any Clinical Trial, (e) any material change to the randomization procedure for, or the duration of treatment and doses to be administered to, the cohorts in any Clinical Trial, and (f) removal or modification of any material Clinical Trial interim analysis criteria and procedures.

1.54 “GAAP” means United States generally accepted accounting principles consistently applied.

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**1.55** “GCP” or “Good Clinical Practices” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Parts 50 and 56 and the guidelines entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.56** “Generic Product” means, with respect to a Product in a country in the Territory, any product sold by a Third Party (including a “generic product”) approved in such country for sale in reliance on a prior approval of a Product, under Section 505(j) of the Federal Food, Drug and Cosmetic Act, or a successor or foreign equivalent applicable Law, by way of an abbreviated regulatory mechanism by the Regulatory Authority in such country, which product meets the equivalency determination by the applicable Regulatory Authority (including a determination that the product is “comparable”, “interchangeable”, “bioequivalent”, “biosimilar” or other term of similar meaning, with respect to such Product), as is necessary to permit substitution of one product for another product by a pharmacist under applicable Laws without intervention by a prescribing physician. A product shall not be considered to be a Generic Product if (a) Janssen or any of its Affiliates or sublicensees is or was involved in the Development or Commercialization of such product, or (b) such product is Commercialized by any Third Party who obtained such product in a chain of distribution that included Janssen or any of its Affiliates or sublicensees.

**1.57** “GLP” or “Good Laboratory Practices” means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.58** “GMP” or “Good Manufacturing Practices” means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws and regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by the EMA or other Regulatory Authorities, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

**1.59** “Governmental Authority” means any multi-national, national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.60** “Housemark” means the corporate name and logo of Janssen or Theravance or any of their respective Affiliates, together with any derivative marks of such name or logo, as identified by one Party to the other from time to time for inclusion on the Labeling for the Products in the Field, as may be updated from time to time by the applicable Party with reasonable notice to the other.

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**1.61** “HSR Act” means the Hart-Scott-Rodino Anti-Trust Improvements Act of 1976, as amended.

**1.62** “IBD Indication” means any chronic intestinal disease that is characterized by inflammation of the bowel, including ulcerative colitis (UC) and Crohn’s disease (CD), celiac disease and immune checkpoint inhibitor (ICI) induced colitis.

**1.63** “ICH” means International Conference on Harmonisation.

**1.64** “IND” means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to a Governmental Authority in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.65** “Indication” means a separately defined, well-categorized class of human disease or condition for which a separate MAA (including any extensions or supplements) may be filed with a Regulatory Authority. For clarity, if an MAA is approved for a Product in a particular Indication and patient population, a label expansion for such Product to include such Indication in a different patient population shall not be considered a separate Indication. For further clarity, all subtypes of a particular tumor type and all treatments thereof, including all lines of treatment shall be deemed the same Indication.

**1.66** “Initial Trials” means the following pair of Clinical Trials of the Initial Product:

(a) A Phase 2 Clinical Trial in Crohn’s disease, as described in the attached Clinical Development Plan; and

(b) The first cohort of two hundred forty (240) subjects in the Phase 2/3 Clinical Trial in Ulcerative Colitis, as described in the attached Clinical Development Plan (“Phase 2/3 UC Trial”).

**1.67** “Invention” means any Know-How, process, method, composition of matter, article of manufacture, invention, discovery or finding, patentable or otherwise, that is first made or generated as a result of a Party (acting solely or jointly with the other Party) exercising its rights or carrying out its obligations pursuant to the Collaboration under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights in and to any of the foregoing.

**1.68** “Irreversible JAK3 Selective Inhibitor” means a molecule which selectively and irreversibly inhibits the human recombinant JAK3 member of the Janus kinase (JAK) family in both biochemical and cellular assays. [\*\*\*].

**1.69** “J&J Universal Calendar” means the calendar of a particular period of twelve (12) months that constitutes a financial year for the purposes of Johnson & Johnson, a New Jersey corporation and the ultimate parent company of Janssen and its Affiliates.

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**1.70** “JAK Inhibitor” means a molecule which selectively inhibits the human recombinant of any member of the Janus kinase (JAK) family in both biochemical and cellular assays.

**1.71** “Know-How” means any non-public or proprietary information, inventions, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, Regulatory Materials, information and submissions pertaining to, or made in association with, filings with any Regulatory Authority or patent office, data (including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

**1.72** “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

**1.73** “Labeling” means any and all labels, labeling, packaging, package inserts and outserts, labels for samples, and promotional materials for the Products in the Field in the Territory.

**1.74** “Lunar Compound” means each of (a) TD-1473; (b) TD-3504; (c) any compound disclosed by the TD-1473 and TD-3504 Patent Families.

**1.75** “Lunar Product” means any Product containing a Lunar Compound.

**1.76** “Manufacturing” means any activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a Compound or Product, directly or through one or more Third Parties. When used as a verb, “Manufacture” means to engage in Manufacturing activities.

**1.77** “Marketing Approval” means, with respect to a Product, any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any Regulatory Authority that are necessary to market and/or sell such Product in a country or jurisdiction for one or more uses, including any pricing and reimbursement approvals that are necessary to conduct a launch of such Product in such country or jurisdiction (even if such pricing and reimbursement approvals are not legally required to launch such product in such country or jurisdiction).

**1.78** “Marketing Authorization Application” or “MAA” means an application to the appropriate Regulatory Authority for Marketing Approval, including an NDA.

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**1.79** “Material Safety Issue” means the occurrence of any significant safety-related event, incident or circumstance with respect to a Compound or Product that leads a Party to reasonably determine that [\*\*\*]. Examples of Material Safety Issues include [\*\*\*].

**1.80** “Net Sales” means the gross amounts invoiced or accrued on sales of a Product by Janssen, or any of its Affiliates or sublicensees, to a Third Party purchaser in an arm’s-length transaction, less the following customary and commercially reasonable deductions, determined in accordance with U.S. GAAP and internal policies and procedures of Janssen and actually taken, paid, accrued, allocated, or allowed based on good faith estimates:

(a) trade, cash and/or quantity discounts, allowances, and credits, excluding commissions for commercialization;

(b) excise taxes, use taxes, tariffs, sales taxes and customs duties and/or other government charges imposed on the sale of Products (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable), specifically excluding, for clarity, any income taxes assessed against the income arising from such sale;

(c) compulsory or negotiated payments and cash rebates or other expenditures to governmental authorities (or designated beneficiaries thereof) in the context of any national or local health insurance programs or similar programs, including, but not limited to, pay for performance agreements, risk sharing agreements and government-levied fees;

(d) rebates, chargebacks, administrative fees, and discounts (or equivalent thereof) to managed health care organizations, group purchasing organizations, insurers, pharmacy benefit managers (or equivalent thereof), specialty pharmacy providers, governmental authorities, or their agencies or purchasers, reimbursers, or trade customers, as well as amounts owed to patients through co-pay assistance cards or similar forms of rebate to the extent the latter are directly related to the prescribing of the Product;

(e) outbound freight, shipment, insurance and other distribution costs to the extent included in the price and separately itemized on the invoice price;

(f) retroactive price reductions, credits or allowances actually granted upon claims, rejections or returns of the Product, including for recalls or damaged or expired goods, billing errors and reserves for returns;

(g) any invoiced amounts that are not collected, and are written off, or reserved as bad debt by Janssen or its Affiliates; and

(h) any deductions in the context of payments that are due or collected significantly after invoice issuance.

All the aforementioned deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount verifiable based on Janssen’s and its Affiliates’ reporting

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system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to the Product and other products of Janssen and its Affiliates and sublicensees such that the Product does not bear a disproportionate portion of such deductions. 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.

Sales of a Product by and between Janssen and any of its Affiliates or sublicensees shall not be considered sales to unaffiliated Third Parties and shall be excluded from Net Sales calculations for all purposes as long as such Product is subsequently resold to an unaffiliated Third Party. Only a single sales transaction with respect to a particular unit of Product, made at the time Janssen or any of its Affiliates or sublicensees sells such unit of Product to an unaffiliated Third Party purchaser in arms-length transaction, will qualify as the basis for determining the Net Sales amount for such unit of Product.

For the avoidance of doubt, the following sales of a Product shall be excluded from Net Sales calculations for all purposes: (i) transfer or dispositions of reasonable quantities of samples of such Product at no cost for promotional or educational purposes, as samples or donations, or for patient assistance, testing marketing programs or other similar programs at no cost; and (ii) use or sale of such Product for Clinical Trial or other scientific testing purposes, early access programs (such as to provide patients with such Product prior to Marketing Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

**1.81** “New Partnership Audit Procedures” means the amendments to the Tax Code that were enacted as section 1101 of the Bipartisan Budget Act of 2015, P.L. 114-74.

**1.82** “Opt-In Date” means the date on which Theravance receives the Opt-In Exercise Fee.

**1.83** “Opt-In Period” means the period beginning on the Effective Date and ending on the earlier of (a) the date that is three (3) months after Janssen’s receipt of the Triggering Data Package After Phase 2 (as such date may be extended in accordance with Section 2.1(a)) or (b) the date that Janssen provides Theravance with its Exercise Notice in accordance with Section 2.1(b).

**1.84** “Other Indication” means an IBD Indication other than a Primary Indication.

**1.85** “Out-of-Pocket Costs” means amounts paid to Third Party vendors, contractors or consultants for services or materials provided by them directly in the performance of Development and Commercialization activities, to the extent such services or materials apply directly to the Product (or such amounts paid to Third Parties for other activities not included in determination of Development Costs or Allowable Expenses, but for which sharing of Out-of-Pocket Costs is otherwise specified in this Agreement). For clarity, Out-of-Pocket Costs do not include payments for the Parties’ or their Affiliates’ employee salaries or benefits, facilities, utilities, general office or facility supplies, insurance, information technology, capital expenditures or the like.

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**1.86** “Patent Rights” means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) any other form of government-issued right substantially similar to any of the foregoing, and (f) all United States and foreign counterparts of any of the foregoing.

**1.87** “Phase 1 Clinical Trial” means a study in humans which provides for the first introduction into humans of a Product, conducted in normal volunteers or patients to generate information on product safety, tolerability, pharmacological activity or pharmacokinetics, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(a) or its foreign equivalents.

**1.88** “Phase 1(b) Clinical Trial” means a study in humans which provides for the first introduction of a pharmaceutical product into patients having the disease of interest with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner which is consistent with U.S. 21 C.F.R. § 312.21(a) or its foreign equivalents.

**1.89** “Phase 2 Activities” means the Initial Trials and any associated Development activities set forth in the Clinical Development Plan.

**1.90** “Phase 2 Clinical Trial” means a study in humans of the safety, dose ranging and efficacy of a Product, which is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial or to file for accelerated approval, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(b) or its foreign equivalents.

**1.91** “Phase 2(a) Clinical Trial” means a pilot Phase 2 Clinical Trial in the relevant human patient population for the purpose of determining the safe and effective dose range for the proposed therapeutic indication of a pharmaceutical product and other characteristics of safety and efficacy.

**1.92** “Phase 3 Activities” means the Phase 3 Clinical Trials and any associated Development activities set forth in the Clinical Development Plan, including Pre-Opt-In Phase 3 Activities.

**1.93** “Phase 3 Clinical Trial” means a controlled study in humans of the efficacy and safety of a Product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file for Marketing Authorization, or otherwise consistent with the requirements of U.S. 21 C.F.R. §312.21(c) or its foreign equivalents.

**1.94** “Phase 3 CMC Development Costs” means the Collaboration CMC Costs incurred by a Party or any of its Affiliates with respect to the Collaboration CMC Activities for the Phase 3 Activities.

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**1.95** “Phase 3 Development Costs” means (a) Out-of-Pocket Costs and (b) Development FTE Costs, in each case, in support of Phase 3 Activities, including Phase 3 CMC Development Costs.

**1.96** “Phase 4 Clinical Trial” means a study in humans of a product that is designed to identify and evaluate the long-term effects of the Product.

**1.97** “Primary Call” means, with respect to a Product, a one-on-one in-person contact in which a sales representative makes a presentation, including selling message and features and benefits of such Product to a healthcare professional having prescribing authority within the target audience, during which contact such Product is the primary focus of the presentation and is presented in the first product position.

**1.98** “Primary Indication” means Ulcerative Colitis (UC) and/or Crohn’s Disease (CD).

**1.99** “Product” means any pharmaceutical product for Covered Delivery, including all such forms, presentations, strengths, doses and formulations thereof, containing one or more Compounds, alone or in combination with each other, but excluding Combination Products. [\*\*\*]. The Product Developed by Theravance for use in the Initial Trials, which contains the TD-1473 as its sole active pharmaceutical ingredient, may be referred herein to as the “Initial Product.”

**1.100** “Proof of Activity Trial” means, with respect to a Solar Product, the first Clinical Trial in patients of such Solar Product as agreed by the Parties pursuant to Section 2.5(b) conducted by or on behalf of Theravance or its Affiliates, which may be a Phase 1(b) Clinical Trial or Phase 2(a) Clinical Trial.

**1.101** “Qualified Change of Control” means, with respect to Theravance, a Change of Control in which the Acquiring Entity, as of the time of such Change of Control, (x) has a field sales force (whether its own or a contract sales organization) in the United States targeting gastroenterologists that promotes any pharmaceutical product that has Marketing Approval for any Primary Indication or for Celiac Disease or (y) would reasonably be likely to [\*\*\*].

**1.102** “Regulatory Authority” means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Marketing Approval in such country or jurisdiction.

**1.103** “Regulatory Exclusivity” means any exclusive marketing rights or data exclusivity rights conferred by any applicable Regulatory Authority or Governmental Authority with respect to a Product, other than Patent Rights (e.g., pediatric exclusivity or any applicable data protection exclusivity).

**1.104** “Regulatory Materials” means regulatory applications, submissions, notifications, communications, correspondence, registrations, Marketing Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction, including INDs and MAAs.

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**1.105** “Secondary Call” means, with respect to a Product, a one-on-one in-person contact in which a sales representative makes a presentation, including selling message and features and benefits of such Product to a healthcare professional having prescribing authority within the target audience, in which such Product is presented in the second product position and no more than two (2) products other than such Product are also presented.

**1.106** “Solar Compound” means a product candidate compound from the Solar Program that is disclosed in the Solar Patent Family, including the compounds referred to internally by Theravance as [\*\*\*], which are disclosed in the Solar Patent Family described in Section 1.107(a).

**1.107** “Solar Patent Family” means (a) the patents listed on Exhibit N and all Patent Rights therein and (b) any other Patent Rights Controlled by Theravance prior to the Effective Date or during the Term that Cover inventions arising from the Solar Program.

**1.108** “Solar Program” means Theravance’s GI-restricted Irreversible JAK3 Selective Inhibitor research and development program.

**1.109** “Solar Product” means any Product containing a Solar Compound.

**1.110** “Tax” or “Taxes” means any present or future taxes, levies, imposts, duties, charges, withholdings, assessments or fees in the nature of a tax (including penalties and additions to tax and interest thereon).

**1.111** “Tax Code” means the U.S. Internal Revenue Code of 1986, as amended.

**1.112** “Tax Representative” means the “partnership representative” defined in section 6223 of the Tax Code (as amended by the New Partnership Audit Procedures).

**1.113** “TD-1473” means Theravance’s proprietary compound referred to as TD-1473 and having the chemical structure set forth on Exhibit B.

**1.114** “TD-1473 and TD-3504 Patent Families” means the patents listed on Exhibit A and all Patent Rights therein.

**1.115** “TD-3504” means Theravance’s proprietary compound referred to as TD-3504 and having the chemical structure set forth on Exhibit C.

**1.116** “Territory” means all countries of the world.

**1.117** “Theravance IP” means the Theravance Know-How and Theravance Patent Rights.

**1.118** “Theravance Know-How” means all Know-How used in or otherwise relating to a Compound or otherwise used by Theravance in the Development, manufacture and Commercialization of a Compound or Product that either (i) is Controlled by Theravance or any of its Affiliates on the Effective Date or (ii) comes into the Control of Theravance or any of its Affiliates during the Term. For clarity, Theravance Know-How includes the Know-How within Sole Inventions owned by Theravance and Theravance’s and its Affiliates’ interest in Joint

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Inventions, in each case to the extent that the foregoing are necessary or useful to Develop, Manufacture, or Commercialize any Compound or Product.

**1.119** “Theravance Patent Rights” means any Patent Rights that (a) are Controlled by Theravance or its Affiliates as of the Effective Date or at any time during the Term, and (b) Cover any Compound (including composition of matter of the Compound, compositions and formulations containing the Compound, and methods of making or using the Compound), Initial Product or Theravance Know-How, including any and all Patent Rights listed on Exhibit A, Patent Rights claiming Sole Inventions owned by Theravance and Theravance’s and its Affiliates’ interest in Joint Patent Rights, in each case to the extent that the foregoing are necessary or useful to Develop, Manufacture or Commercialize any Compound or Product.

**1.120** “Third Party” means any entity other than Theravance or Janssen or an Affiliate thereof.

**1.121** “Third Party Blocking Intellectual Property Rights” means Patent Rights Controlled by a Third Party that Cover a Compound or a Product.

**1.122** “Triggering Data Package After Phase 2” means, with respect to the Compounds, (a) the Data with respect to such Compounds generated by Theravance pursuant to the Initial Trials with completed statistical analysis, including tables, listings and figures, as well as (b) any other Data from the Initial Trials or any sub-studies thereof (for example, biomarker or pharmacokinetic studies), that, in the case of such sub-studies, are further defined by the JDC and approved by the JSC, which are reasonably necessary for Janssen to decide whether to exercise the Option in accordance with Section 2.1.

**1.123** “United States” or “U.S.” means the United States of America, including all possessions and territories thereof.

**1.124** “Valid Claim” means (a) a claim of any issued, unexpired patent or (b) a pending claim of a pending patent application during the [\*\*\*] from the earliest priority date claimed by such pending patent application which has not been dedicated to the public, disclaimed, revoked, abandoned or held invalid or unenforceable by a court or other government agency of competent jurisdiction in a decision from which no appeal can be taken or is otherwise not taken.

**1.125** “VAT” means value-added tax, goods and services tax or similar tax, including any value added tax within the meaning of European Council Directive 2006/112/EC as transposed into the applicable Laws of the relevant member state and any other similar turnover tax in any other relevant non-EU jurisdiction.

**1.126** Interpretation. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (ii) the word “or” shall have its inclusive meaning of “and/or;” (iii) the word “notice” shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words “hereof,” “herein,” “hereunder,” “hereby” and derivative or

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similar words refer to this Agreement (including any Exhibits); (v) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, approved meeting minutes, letter or otherwise; (vi) words of any gender include the other gender; and (vii) words using the singular or plural form also include the plural or singular, respectively where appropriate given the context; and (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof.

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| <b>Defined Terms</b>         | <b>Sections</b>  |
|------------------------------|------------------|
| [***]                        | 2.5(a)           |
| Additional Compound Notice   | 2.5(a)           |
| Agreement                    | Preamble         |
| Alliance Manager             | 3.4              |
| Allowable Expenses           | <u>Exhibit M</u> |
| Anti-Corruption Laws         | 8.1(d)(i)        |
| Assessment Period            | 2.5(a)           |
| Audited Site                 | 4.4(i)           |
| Breaching Party              | 11.3             |
| CAPA                         | 4.4(g)           |
| [***]                        | <u>Exhibit M</u> |
| Claims                       | 9.1              |
| Clearances                   | 2.2              |
| CMC Budget                   | 4.2(c)(vi)       |
| Code                         | 13.3(a)          |
| COGS                         | <u>Exhibit M</u> |
| Collaboration Plans          | 4.2(a)           |
| Collaboration Records        | 4.4(j)(i)        |
| Commercial License           | 2.1(b)           |
| Commercialization Agreement  | 5.2(c)           |
| Commercialization Option     | 5.2(a)           |
| Commercialization Plan       | 5.3              |
| Committee                    | 3.1(a)           |
| Competing Program            | 2.6(d)           |
| Conducting Party             | 4.4(a)           |
| Cost of Goods Sold           | <u>Exhibit M</u> |
| Cost Variances               | <u>Exhibit M</u> |
| CPR Mediation Procedure      | 12.2(b)          |
| CPR Rules                    | 12.2(c)          |
| CWG                          | 3.5              |
| Cure Period                  | 11.4             |
| Deadlocked Matter            | 3.2(b)           |
| Defending Party              | 9.3              |
| Deferrable Costs             | 6.3(c)           |
| Dispute                      | 12.1             |
| [***]                        | <u>Exhibit M</u> |
| Divestiture                  | 2.6(d)(ii)       |
| DOJ                          | 2.2              |
| Effective Date               | Preamble         |
| Excluded Claim               | 12.2(a)          |
| Exercise Notice              | 2.1(b)           |
| Ex-U.S. Territory Activities | 6.16(b)          |
| FCPA                         | 8.1(d)(i)        |
| Finance Working Group        | 3.6              |

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|                                      |                  |
|--------------------------------------|------------------|
| Foreign Authorities                  | 2.2              |
| FTC                                  | 2.2              |
| [***]                                | <u>Exhibit M</u> |
| [***]                                | <u>Exhibit M</u> |
| [***]                                | <u>Exhibit M</u> |
| HIPAA Authorization                  | 4.4(d)           |
| Indemnified Party                    | 9.4              |
| Indemnifying Party                   | 9.4              |
| Initial Development Period           | 2.1(a)           |
| Janssen                              | Preamble         |
| Janssen Indemnitees                  | 9.1              |
| Janssen Sole Patent Rights           | 7.3(a)           |
| JDC                                  | 3.3(b)           |
| JMC                                  | 3.3(a)           |
| Joint Inventions                     | 7.1(b)           |
| Joint Patent Rights                  | 7.1(b)           |
| Joint Steering Committee             | 3.1(a)           |
| JSC                                  | 3.1(a)           |
| Losses                               | 9.1              |
| Lunar Products                       | 2.5(b)(iv)       |
| Manufacturing Party                  | 4.4(h)           |
| [***]                                | <u>Exhibit M</u> |
| [***]                                | <u>Exhibit M</u> |
| Milestone 1                          | 6.4              |
| Milestone 2                          | 6.4              |
| Non-Defending Party                  | 9.3              |
| Opt-In Exercise Fee                  | 6.2              |
| Option                               | 2.1(b)           |
| Option Completion Date               | 2.2              |
| [***]                                | <u>Exhibit M</u> |
| Other Costs Not Included in Standard | <u>Exhibit M</u> |
| Other Income                         | <u>Exhibit M</u> |
| Parties                              | Preamble         |
| Partnership                          | 6.16(a)          |
| Party                                | Preamble         |
| Payee                                | 6.15(b)          |
| Paying Party                         | 6.9(d)           |
| Payor                                | 6.15(b)          |
| [***]                                | 2.5(b)           |
| Phase 2 Budget                       | 4.2(b)(i)        |
| POA Results                          | 2.5(b)(ii)       |
| PPACA                                | <u>Exhibit M</u> |
| Pre-Opt-In Phase 3 Activities        | 4.2(b)(ii)       |
| Product Marks                        | 7.8              |
| Profit (Loss)                        | <u>Exhibit M</u> |

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|                                     |                  |
|-------------------------------------|------------------|
| Quarterly Report                    | 6.9(b)           |
| [***]                               | <u>Exhibit M</u> |
| Receiving Party                     | 6.9(d)           |
| Recording Party                     | 6.13             |
| Royalty Term                        | 6.8(b)           |
| Second Opt-In Fee                   | 2.5(b)(ii)       |
| [***]                               | <u>Exhibit M</u> |
| [***]                               | <u>Exhibit M</u> |
| [***]                               | <u>Exhibit M</u> |
| [***]                               | 2.5(b)(iv)       |
| Solar Co-Funding Election           | 2.5(b)           |
| Solar Opt-In Period                 | 2.5(b)(ii)       |
| Solar Option                        | 2.5(b)(ii)       |
| [***]                               | 2.5(b)(iv)       |
| Sole Inventions                     | 7.1(a)           |
| Specified Percentage                | 6.3(b)           |
| Standard Cost of Goods Manufactured | <u>Exhibit M</u> |
| Subcommittee                        | 3.1(a)           |
| Term                                | 11.1             |
| Terminating Party                   | 11.4             |
| Termination IP                      | 11.6(c)(ii)      |
| Theravance                          | Preamble         |
| Theravance Indemnitees              | 9.2              |
| Theravance Sole Patent Rights       | 7.3(b)(i)        |
| [***]                               | <u>Exhibit M</u> |
| Trade Control Laws                  | 8.1(e)(i)        |
| Transferred Regulatory Materials    | 11.6(d)          |
| UKBA                                | 8.1(d)(i)        |

## ARTICLE 2

### OPTION, LICENSES AND EXCLUSIVITY

#### 2.1 Option to Janssen.

(a) **Initial Development Period.** Subject to the terms of this Section 2.1(a), Theravance will perform, in collaboration with Janssen, certain Development activities with respect to the Initial Product for the Primary Indications during the portion of the Development Term prior to the expiration of the Opt-In Period (the “Initial Development Period”). During the Initial Development Period, the Parties shall use Commercially Reasonable Efforts to Develop the Products in accordance with the Collaboration Plans (as they may be amended from time-to-time in accordance with Section 4.2(b) or Section 6.3(c)). Theravance hereby grants a non-exclusive license to Janssen under Theravance IP for purposes of conducting such Development activities as are assigned to Janssen in the Collaboration Plans, during the Initial Development Period. Without

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limiting the foregoing, Theravance shall use Commercially Reasonable Efforts to conduct the Initial Trials and any other activities assigned to Theravance in the Collaboration Plans and decided by the JSC to be performed prior to the Opt-In Date as set forth in the Collaboration Plans, at its own expense as set forth in the Phase 2 Budget, subject to Section 6.3(c). Promptly following completion of the Initial Trials, Theravance shall provide Janssen with the Triggering Data Package After Phase 2. In addition, following Theravance's receipt of Janssen's written request made within [\*\*\*] of receipt of the Triggering Data Package After Phase 2, Theravance shall, within [\*\*\*] of such request, provide Janssen with any additional information within Theravance's Control that is reasonably requested by Janssen with respect to the Initial Compounds or the Initial Product. If any of the information so requested is not within Theravance's Control, Theravance shall notify Janssen in writing during such [\*\*\*] period that Theravance does not have such additional information. The deadline for Janssen to provide the Exercise Notice at the end of the Opt-In Period shall be extended until [\*\*\*] after Theravance shall have delivered such additional information reasonably requested by Janssen; provided that if Theravance shall in good faith reasonably believe it has provided such additional information (or that it does not have such additional information), it may deliver a written notice to that effect and stating the date on which such delivery occurred (or that it does not have such additional information), in which case the deadline for Janssen to provide the Exercise Notice at the end of the Opt-In Period will not be so extended, unless Janssen in good faith reasonably believes any such additional information that Theravance has and is reasonably requested by Janssen remains undelivered and, within [\*\*\*] after delivery of such notice by Theravance, delivers a written notice to Theravance to that effect (setting forth with specificity what additional information has not yet been delivered). The Triggering Data Package After Phase 2, and all additional information provided by Theravance pursuant to this Section 2.1(a) shall be the Confidential Information of Theravance, subject to the protections of Article 10.

**(b) Option and Commercial License.** Subject to the terms and conditions of this Agreement, Theravance hereby grants Janssen an exclusive option (the "Option") to obtain an exclusive (even as to Theravance), royalty-bearing and sublicensable (subject to Section 2.1(d)) license, under the Theravance IP (i) to Develop, make, have made, use, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Manufacture the Compounds, in each case solely for incorporation into Products and otherwise in connection with Developing and Commercializing Products, and (ii) to Develop, make, have made, use, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit, Manufacture and Commercialize the Products; in each case ((i) and (ii)), in the Field in the Territory (the "Commercial License"). Janssen may exercise the Option at any time during the Opt-In Period by providing Theravance with written notice of such exercise ("Exercise Notice"). After such exercise and subject to receipt of any necessary Clearances in accordance with Section 2.2, Janssen will pay Theravance the Opt-In Exercise Fee. Effective upon Janssen's exercise of the Option and payment of the Opt-In Exercise Fee, Theravance shall grant, and hereby grants, to Janssen the Commercial License, subject to the terms and conditions of this Agreement. Further, effective as of the Opt-In Date, Theravance shall grant, and hereby grants, to Janssen a non-exclusive license to use the Theravance Housemark to the extent included on the Labeling of the Products in the Field in accordance with Section 5.6, solely for purposes of Manufacturing and Commercializing the Products in the Field in the Territory.

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(c) **Research License.** As of the Effective Date of this Agreement, Theravance hereby grants, on behalf of itself and its Affiliates, to Janssen a non-exclusive, perpetual, world-wide, royalty-free license (with the right to sublicense to its Affiliates and Third Party collaborators) to practice Collaboration Know-How and Theravance Know-How to which it is exposed pursuant to the Collaboration solely for purposes of conducting non-commercial, internal research activities by Janssen and its Affiliates in furtherance of their efforts to identify new therapeutic and diagnostic agents. This Section 2.1(c) shall survive any termination or expiration of this Agreement, but, for clarity, shall not grant Janssen any rights under any Theravance Patent Rights.

(d) **Sublicenses.** Effective as of the Opt-In Date, Janssen shall have the right to grant sublicenses (including, for the avoidance of doubt, with respect to Development, Manufacturing and Commercialization) through multiple tiers, under the Commercial License, to its Affiliates and/or to Third Parties, so long as Janssen does so in a manner that is consistent with Janssen's general process for approving sublicensees. Each agreement in which Janssen grants a sublicense under the Theravance IP shall be consistent with the relevant terms and conditions of this Agreement. Without limiting Janssen's diligence obligations set forth elsewhere in this Agreement, if Janssen sublicenses to a Third Party all or substantially all responsibility for Commercializing the Product in a particular jurisdiction, Janssen's sublicense agreement with such sublicensee shall obligate the sublicensee to use efforts in its Commercialization of the Product in such jurisdiction at least equivalent to those Commercially Reasonable Efforts that Janssen is obligated to use to Commercialize the Product in such jurisdiction under this Agreement. Janssen shall be liable to Theravance for the performance of its direct and indirect sublicensees, including their compliance with the provisions of this Agreement. Twice per year, each Party shall provide the other with written notice of any sublicenses to Third Parties granted under the Commercial License during such period.

**2.2 Antitrust.** Upon Theravance's receipt of the Exercise Notice, each Party will use Commercially Reasonable Efforts to take all actions necessary, proper or advisable under Antitrust Law to consummate the Option as soon as practicable after the date on which Janssen provides the Exercise Notice to Theravance, including, as necessary, (a) preparing and filing with the U.S. Federal Trade Commission (the "**FTC**") and the Antitrust Division of the U.S. Department of Justice (the "**DOJ**"), and the notification and report forms relating to the exercise of the Option and Commercial License as required by the HSR Act, (b) preparing and filing with the appropriate governmental bodies of any foreign antitrust authority identified by Janssen ("**Foreign Authorities**"), and comparable notification forms required by the merger notification or control laws of any other applicable jurisdiction and (c) taking all steps as may be necessary to obtain all such waiting period expirations or terminations, consents, clearances, waivers, licenses, registrations, permits, authorizations, orders and approvals (collectively, "**Clearances**"). Each of Janssen and Theravance shall, in connection with the efforts referenced in this Section 2.2 to obtain all applicable Clearances for the Option and Commercial License under any applicable Antitrust Law, (i) to the extent reasonably practicable, not participate in or attend any meeting, or engage in any substantive conversation with, any Governmental Authority in respect of the transactions contemplated hereby without the other, (ii) to the extent reasonably practicable, give the other

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reasonable prior notice of any such meeting or conversation, (iii) in the event one party is prohibited by applicable Laws or by the applicable Governmental Authority from participating in or attending any such meeting or engaging in any such conversation, keep such Party reasonably apprised with respect thereto, (iv) cooperate in the filing of any substantive memoranda, white papers, filings, correspondence, other substantive written communications or Regulatory Materials explaining or defending this Agreement and the transactions contemplated hereby, articulating any regulatory or competitive arrangement or responding to requests or objections made by any Governmental Authority, (v) provide each other or the outside counsel of the other Party with complete and accurate copies to the other of all filings, submissions, correspondence and other substantive written communications (and memoranda setting forth the substances thereof) between it and its Affiliates and their respective representatives, on the one hand, and any Governmental Authority or members of any Governmental Authority's staff, on the other hand, with respect to this Agreement and the transactions contemplated hereby, subject to (a) the sharing of competitively sensitive information on a confidential outside counsel only basis (which must be redacted before sharing with the other Party), and (b) the redaction of valuation material or information subject to attorney-client privilege (including when shared with the outside counsel of the other Party), and (vi) consider in good faith the views of the other in connections with such communications. The Parties will jointly control the strategy relating to Clearances for the Products under the Antitrust Laws; provided that Janssen shall control all communications with the FTC, DOJ, and Foreign Authorities with respect to its filings for Clearances for the Products, and Theravance shall control all communications with the FTC, DOJ, and Foreign Authorities with respect to its filings for Clearances for the Products. Notwithstanding the foregoing or any other provision of this Agreement, in no event shall either Party be required to offer, accept or agree to (1) sell, divest, dispose of or hold separate (including through a license or a reversion of licensed or assigned rights) any portion of the businesses, operations, assets or product lines of itself or its Affiliates or (2) otherwise take any action that limits the freedom of action with respect to, or its ability to retain, any of its businesses, operations, assets or product lines or those of its Affiliates. Each Party shall bear its own costs and expenses associated with the filings (including filing fees, which, for clarity, shall be borne by Janssen as licensee) and other actions contemplated by this Section 2.2. In the event Janssen has not obtained all necessary clearances pursuant to this Section 2.2 within [\*\*\*]. After obtaining of all necessary Clearances pursuant to this Section 2.2, Janssen and Theravance shall mutually agree on a date for consummation of the Option, which date shall be no later than [\*\*\*] after the date of obtaining all necessary Clearances (such date, the "Option Completion Date"). On the Option Completion Date, Janssen shall pay Theravance the Opt-In Exercise Fee.

### **2.3 License to Theravance.**

(a) Effective as of the Opt-In Date, subject to the terms and conditions of this Agreement, Janssen hereby grants Theravance a non-exclusive license under the Janssen's Sole Inventions, including any Janssen Sole Patent Rights, for purposes of conducting such Development activities as are assigned to Theravance in the Collaboration Plans, during the Development Term.

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(b) Effective as of the Opt-In Date, subject to the terms and conditions of this Agreement, Janssen hereby grants Theravance a non-exclusive license under the Theravance IP

for purposes of conducting: (i) such Development activities as are assigned to Theravance in the Collaboration Plans, during the Development Term; and (ii) such Commercialization activities as are assigned to Theravance in the Commercialization Plan or the Commercialization Agreement.

(c) If this Agreement terminates prior to the Opt-In Date, Janssen shall grant and hereby grants Theravance a non-exclusive, worldwide, perpetual, irrevocable, royalty-free license, including the right to grant and authorize sublicenses, under Janssen's Sole Inventions made during the period between the Effective Date and expiration of the Opt-In Period, including any Janssen Sole Patent Rights therein, to Develop, make, have made, use, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit, Manufacture and Commercialize the Compounds and the Products.

**2.4 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party. All rights not otherwise expressly granted hereunder by a Party shall be retained.

## **2.5 Other Rights.**

(a) **Additional Compounds.** [\*\*\*], Theravance may propose that such Additional Compound be included in this Agreement by providing Janssen with written notice of such Additional Compound (each, an "Additional Compound Notice"), which notice shall include any Data that has been generated by or on behalf of Theravance or its Affiliates that is reasonably necessary for Janssen to assess whether to include such Additional Compound under this Agreement. Upon receipt of an Additional Compound Notice, Janssen shall have a period of [\*\*\*] (the "Assessment Period") to assess whether it desires to include such Additional Compound within the Compounds and provide notice to Theravance of such determination. Such Assessment Period can be mutually extended by the Parties. [\*\*\*].

### **(b) Solar Program.**

(i) Unless non-GLP toxicology studies show results that would preclude further development, Theravance shall conduct the GLP toxicology studies for the lead Solar Compound (the "GLP Tox Studies"). Subject to successful completion of the GLP Tox Studies (with successful completion to be determined consistent with the FDA's *Guidance for Industry: M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals* (January 2010) ("FDA Guidance")), [\*\*\*].

(ii) If Janssen provides Theravance with its Exercise Notice in accordance with Section 2.1(b), Solar Compounds shall constitute Compounds for all

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purposes under this Agreement, and the JSC shall determine the Development plan, if any, for the Solar Program.

**(iii)** If Janssen provides Theravance with its Exercise Notice in accordance with Section 2.1(b), and states in such notice that, taking account of the results

of the Initial Trials, [\*\*\*], then (1) Solar Compounds shall constitute Compounds for all purposes under this Agreement, (2) Janssen shall [\*\*\*], (3) the portion of the Opt-In Exercise Fee payable at the Opt-In Date shall be [\*\*\*] and (4) the JSC will evaluate whether a Solar Product may be suitable for use in treating any Primary Indications and, if so, shall develop an appropriate Development plan and budget for investigating such potential use, including a Proof of Activity Trial [\*\*\*]. If the JSC determines to proceed with a POA trial for a Solar Product or to pursue Development of an additional Opt-In Indication for the Initial Product (“Additional Indications”), [\*\*\*]; *provided that* in the event Janssen determines at any point thereafter to cease (in their entirety) development of the Solar Program and Development of all Additional Indications: [\*\*\*]. Similarly, if Janssen decides not to proceed with a POA trial for Solar or an Additional Indication for the Initial Product: [\*\*\*].

**(iv)** If Janssen does not provide Theravance with its Exercise Notice in accordance with Section 2.1(b), then the Lunar Compounds shall cease to be Compounds and the Lunar Products shall cease to be Products for all purposes of this Agreement and upon review of the [\*\*\*] and taking into account publicly available Third Party Irreversible JAK3 Selective Inhibitor data as well as a draft Proof of Activity protocol provided by Theravance, Janssen would have the right to elect to co-fund the first Proof of Activity Trial of a Solar Product (the “Solar Co-Funding Election”). Janssen would exercise the Solar Co-Funding Election by providing Theravance with written notice of such election within [\*\*\*], or such longer period as may be agreed to by the Parties in writing. If Janssen elects to exercise the Solar Co-Funding Election: [\*\*\*]:

[\*\*\*]

[\*\*\*]

[\*\*\*]

**(c)** If Janssen does not provide Theravance with its Exercise Notice in accordance with Section 2.1(b) and does not exercise the Solar Co-Funding Election or, having exercised the Solar Co-Funding Election, does not thereafter opt-in to the [\*\*\*] commercial license provided in the [\*\*\*], then Janssen shall have no further rights with respect to the Solar Compounds or any other Compounds (and, for the avoidance of doubt, the royalty obligation under Section 2.5(b)(iv)(A) shall cease) and this Agreement shall immediately terminate.

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## 2.6 Exclusivity.

(a) **Theravance.** During the Term, Theravance shall not, directly or indirectly through any Affiliate or Third Party, [\*\*\*] unless otherwise permitted under the terms of this Agreement, including as set forth in Section 2.5 above with respect to Solar Compounds and the Solar Program and in this Section 2.6, and with respect to the Products as set forth herein.

(b) **Janssen.** During the Term, Janssen shall not, directly or indirectly through any Affiliate or Third Party, [\*\*\*] unless otherwise permitted under the terms of this Agreement.

(c) **Both Parties.** Subject to the terms of this Section 2.6, during the Term, neither Party shall, directly or indirectly through any Affiliate or Third Party, [\*\*\*].

(d) **Present and Future Activities.** Notwithstanding anything to the contrary herein, but subject to Section 2.6(b), Theravance acknowledges that (i) Janssen and its Affiliates may have present or future activities, initiatives or opportunities, including activities, initiatives or opportunities with Third Parties, involving similar products, programs, technologies or processes that may compete with products, programs, technologies or processes covered by this Agreement; (ii) nothing in this Agreement will be construed as a representation, warranty, covenant or inference that Janssen or its Affiliates [\*\*\*]; and (iii) Janssen or any of its Affiliates may, [\*\*\*] *provided that*, this Section 2.6(d)(iii) does not modify any of the terms and conditions of this Agreement relating to the use or disclosure of Confidential Information or intellectual property of the other Party.

(e) **Acquisition of Competing Product.** In the event that a Third Party becomes an Affiliate of Theravance after the Effective Date through merger, acquisition, consolidation or other similar transaction, and as of the closing date of such transaction, such Third Party is engaged in the research, development, manufacture or commercialization of a product that, if conducted by Theravance, would cause Theravance to be in breach of its exclusivity obligations set forth above in this Section 2.6 (a “Competing Program”), then:

(i) if such transaction results in a Change of Control of Theravance, such new Affiliate shall have the right to continue such Competing Program and such continuation shall not constitute a breach of Theravance’s exclusivity obligations set forth in this Section 2.6; provided that such new Affiliate conducts such Competing Program independently of the activities of this Agreement and does not use any of Janssen’s intellectual property rights or Confidential Information (except as may be separately licensed by Janssen to such new Affiliate) in the conduct of such Competing Program; [\*\*\*]; and

(ii) if such transaction does not result in a Change of Control of Theravance, then Theravance and its new Affiliate shall have [\*\*\*] to wind down or complete the divestiture of such Competing Program, and its new Affiliate’s conduct of such Competing Program during such [\*\*\*] period shall not be deemed a breach of Theravance’s exclusivity obligations set forth above; provided that such new Affiliate conducts such Competing Program during such [\*\*\*] period independently of the activities of this Agreement and does not use any of Janssen’s intellectual property or Confidential Information (except as may be separately licensed by Janssen to such new Affiliate) in the

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conduct of such Competing Program. “Divestiture”, as used in this Section 2.6(e)(ii), means the sale or transfer of rights to the Competing Program to a Third Party without receiving a continuing share of profit, royalty payment or other economic interest in the success of such Competing Program.

### ARTICLE 3 GOVERNANCE

#### 3.1 Joint Steering Committee.

(a) **Formation.** Promptly, and in any event within thirty (30) days after the Effective Date, the Parties shall establish a joint steering committee (the “Joint Steering Committee” or “JSC”) which shall have overall responsibility for the Collaboration established under this Agreement and maintain oversight of the Development and Commercialization of the Product(s) in the Territory. The JSC may from time to time establish one or more subcommittees (each, a “Subcommittee”), to perform certain duties and exercise certain powers of the JSC as expressly delegated by the JSC to such Subcommittee (the JSC and any Subcommittee are each referred to herein as a “Committee”). The JSC will:

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

(b) **Members.** Each Party shall appoint three members to the JSC, each with the requisite experience and seniority to enable such representative to make decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the JSC. Each Party shall appoint one (1) of its representatives as co-chairperson of the JSC. Each Party may replace its representatives at any time upon written notice to the other Party. Neither Party shall appoint any representative to the JSC that is not an employee of such Party or one of its Affiliates without the prior written consent of the other Party. The JSC may change its size from time to time by mutual consent of its members, *provided* that the JSC shall at all times include an equal number of representatives of each Party. Each Party may replace its JSC representatives at any time upon written notice to the other Party.

(c) **Meetings.** The JSC shall meet as necessary, but at least [\*\*\*]. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) by at least [\*\*\*] prior written notice to the other Party, and such Party shall provide the other Party’s member, no later than [\*\*\*] prior to the special meeting, with materials reasonably adequate to enable informed discussion or decision-making, as applicable. The JSC may meet in person, by videoconference

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or by teleconference, as the Parties agree. Each Party shall bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least two (2) (or such other number as is agreed by the JSC) of each Parties' representatives (or their designees) are present or participating in such meeting; provided that if a quorum is not present at the first meeting, the JSC shall reconvene at least two (2) days later and such meeting shall be effective if at least one (1) of each Parties' representatives (or their designees) are present or participating in such meeting.

**(d) Agenda and Minutes.** Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed agenda items in advance of each JSC meeting. Each co-chairperson of the JSC, on an alternating basis, shall prepare and circulate to all members of the JSC for review draft minutes of each JSC meeting within thirty (30) days after such meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JSC, *provided* that, if the Parties cannot agree as to the content of the minutes by the time of the next JSC meeting, such minutes shall be finalized to reflect any areas of disagreement.

### **3.2 Decision Making.**

**(a)** The JSC shall make decisions and take action (1) by consensus of the members present at a meeting, with each Party having one (1) vote irrespective of the number of representatives of such Party in attendance, or (2) by a written resolution signed by at least both co-chairpersons appointed by each Party.

**(b)** If, despite using reasonable efforts, the JSC does not reach consensus on any matter within its decision-making authority (a "Deadlocked Matter") within a period of twenty-one (21) days (or such other period as the Parties may agree in writing) after it has met and attempted to reach such consensus, then either Party may, by written notice to the other Party, refer the Deadlocked Matter to the Executive Officers; *provided, however*, that, if the Executive Officers do not reach agreement on such Deadlocked Matter within thirty (30) days after such Deadlocked Matter is referred to the Executive Officers, then such Deadlocked Matter shall be decided as provided below:

**(i)** prior to the Opt-In Date, Theravance shall have the final decision-making right with respect to any Deadlocked Matter, considering Janssen's comments and suggestions in good faith; and

**(ii)** after the Opt-In Date, Janssen shall have the final decision-making right with respect to any Deadlocked Matter, considering Theravance's comments and suggestions in good faith.

**(iii)** Except as set forth in Section 6.3(c), neither Party shall have the final decision-making right, pursuant to this Section 3.2, with respect to any matter outside of the JSC's decision-making authority, or with respect to whether to effect any Fundamental Development Plan Change, and in the event of a failure to agree with respect

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to a Fundamental Development Plan Change, the Parties shall proceed under the then-current Clinical Development Plan having last been approved by both Parties.

(iv) Except as set forth in Section 6.3(c), neither Party may exercise its final decision-making authority with respect to a Deadlocked Matter to require or cause the other Party to take any action in violation of applicable Laws or that, in such other Party's reasonable determination, is a risk to patients or clinical trial subjects or is otherwise contrary to GCP and ethics or such other Party's compliance policies, or require or cause the other Party to bear any costs other than its agreed upon share of those set forth in then-current Phase 2 Budget, or Phase 3 Development Budget, or to commit additional employee or other resources to conduct Collaboration Activities. Notwithstanding the foregoing, except as set forth in Section 6.3(c), a Party may not exercise such final decision making authority in a manner that would increase the financial obligations of the other Party, and Theravance shall have the right to decide, in its sole discretion, whether to participate in the Commercialization of the Product in the U.S.

(c) The JSC shall have only such powers as are specifically delegated to it hereunder, and for clarity the JSC shall not have any authority or ability to: (1) resolve or conclude any disputes regarding a Party's performance or non-performance of its obligations under this Agreement; (2) modify, amend or waive the terms or conditions of this Agreement; or (3) bind either Party to act or refrain from acting in any manner.

### 3.3 Subcommittees

(a) The Parties shall establish a Joint Manufacturing Committee ("JMC") promptly after establishing the JSC. The purpose of the JMC will be to oversee and coordinate the execution of the Collaboration CMC Activities during the Term, and to review and discuss potential changes to the CMC Development Plan and to manufacturers of Compound API or Product for use in Clinical Trials.

(b) The Parties shall establish a Joint Development Committee ("JDC") within thirty (30) days after the Effective Date to oversee and coordinate the Parties' Development activities pursuant to the Clinical Development Plan during the Development Term and to review and discuss potential changes to the Clinical Development Plan. The JDC shall include representatives from each Party, with Janssen contributing representatives with expertise including clinical operations expertise (to assist with trial design, as well as site identification and engagement), a biomarker expertise, and global and regional regulatory expertise.

(c) As set forth in Section 3.1(a), the JSC may, as necessary or appropriate and agreed to by the JSC, establish other Subcommittees and delegate tasks within its authority as expressly provided for hereunder to such Subcommittees. For clarity, each Subcommittee shall operate in the same manner as the JSC with respect to membership and meetings, *provided* that such Subcommittees shall have no decision-making authority, but shall instead operate by consensus and make recommendations to the JSC with respect to matters within its authority with respect to which it cannot reach consensus.

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**3.4 Alliance Managers.** Promptly after the Effective Date, each Party shall appoint an individual to act as alliance manager for that Party (each, an “Alliance Manager”). The Alliance Manager shall be permitted to attend meetings of the Committees as a non-voting observer, subject to the confidentiality provisions of Article 10. The Alliance Managers shall be the primary point of contact for the Parties with respect to the activities to be conducted under this Agreement. The name and contact information for the Alliance Managers, as well as any replacement(s) chosen by either Party in their sole discretion from time to time, shall be promptly provided to the other Party in writing.

**3.5 Commercialization Working Group.** Promptly, and in any event upon Janssen’s receipt of top line Phase 3 results (or earlier if so determined by the JSC), the Parties shall establish a Commercialization Working Group (the “CWG”) which shall include individuals from each Party with reasonable expertise in the areas of sales operation, sales management and marketing and have overall responsibility for operational Commercialization decisions. Janssen shall provide the Commercial Plan and Budget to the CWG on an annual basis for review and discussion. The CWG will review and discuss the Commercialization Plans and the Commercial Budget, including any updates or amendments thereto, and shall present them to the JSC on an annual basis for comment and endorsement. With regard to the Commercialization Plans and the Commercial Budget, Janssen shall consider the viewpoints of the CWG and JSC in good faith; *provided* that notwithstanding the foregoing or any other provision of this Agreement, Janssen shall have final decision-making authority with regard to all Commercialization decisions, including with respect to the Commercialization Plans and the Commercial Budget.

**3.6 Finance Working Group.** At such time as the JSC deems appropriate, Theravance and Janssen shall establish a joint Finance Working Group (the “Finance Working Group”), which shall report to the JSC. The Finance Working Group shall (a) coordinate and conduct the budgeting, accounting, reporting, reconciliation and other financial activities set forth in this Agreement and (b) perform the other functions that are expressly delegated to the Finance Working Group in this Agreement. The Finance Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting. Without limiting the foregoing, the Finance Committee will provide a forum for the Parties to develop the budgets for the Development and Manufacturing activities hereunder with respect to the Products, including for the Collaboration Plans and all Allowed Expenses, and to track the Parties’ progress against such budgets. The Finance Working Group shall establish reasonable procedures for the Parties to share estimates prior to the end of such Calendar Quarter to enable each Party to meet its quarterly requirements.

**3.7 Discontinuation of Committees.** The activities to be performed by the JSC and its Subcommittees shall solely relate to governance under this Agreement, and are not intended to be or involve the delivery of services. The JSC and each Subcommittee shall continue to exist, unless the Parties mutually agree to disband such Committee, with consent to disband not to be

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unreasonably withheld by either Party, or, after the Opt-In Date, Theravance unilaterally disbands such Committee by providing Janssen with written notice thereof. Once a Committee is disbanded, such Committee shall have no further obligations under this Agreement and, thereafter, each Party shall designate a contact person for the exchange of information under this Agreement or such exchange of information shall be made through the Alliance Managers. In the event a Committee is disbanded, any decisions that are designated under this Agreement as being subject to the review or approval of such Committee shall be made by the Parties directly, subject to the other terms and conditions of this Agreement; provided that final decision making authority for such decisions shall be allocated to the Party having final decision making authority with respect thereto pursuant to Section 3.2(b).

#### **ARTICLE 4 DEVELOPMENT; MANUFACTURE; REGULATORY**

**4.1 Overview.** The Parties agree to conduct Development of Products as provided in this Article 4.

**4.2 Collaboration Plans.**

**(a) General.** The Parties will use Commercially Reasonable Efforts to Develop the Initial Product in accordance with the Clinical Development Plan and CMC Development Plan (together, the “Collaboration Plans”). The initial Collaboration Plans are set forth in Exhibit E and Exhibit F hereto.

**(b) Clinical Development Plan.** The Clinical Development Plan shall contain key Development activities (other than CMC Development Activities) necessary to complete Development of the Initial Product for an IBD Indication through the end of Phase 3, and may also include Development activities with respect to other Compounds and Products mutually agreed upon by the Parties. For clarity, the Parties shall not conduct Development activities with respect to a Compound or Product during the Development Term unless such activities are agreed by the JSC and set forth in the Clinical Development Plan. The Clinical Development Plan shall include a reasonably detailed description of such activities, a timeline for completion of such activities and the deliverables for such activities. Without limiting the foregoing, the Clinical Development Plan shall include:

**(i)** the Initial Trials, which will form the basis of the Triggering Data Package After Phase 2, as well as a budget for the Phase 2 Development Costs broken down by activity and by Calendar Year (the “Phase 2 Budget”);

**(ii)** certain Development activities for Phase 3 Clinical Trials of the Product to commence prior to the Opt-In Date, including certain activities to support the ongoing Phase 2/3 UC Trial, such as the Phase 3 Maintenance Study and the Phase 3 OLE Study (“Pre-Opt-In Phase 3 Activities”); and

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**(iii)** Phase 3 Activities, and a budget for the Phase 3 Development Costs (including the Pre-Opt-In Phase 3 Activities) broken down by activity and by Calendar Year (the “Phase 3 Development Budget”). The initial Phase 3 Development Budget is attached hereto as Exhibit G.

**(c) CMC Development Plan.** The CMC Development Plan shall at all times contain the following CMC Development activities with respect to the Initial Compound and Initial Product, and may also include other CMC Development activities with respect to the Compounds and Products mutually agreed upon by the Parties. The CMC Development Plan shall include a reasonably detailed description of the activities set forth therein, a timeline for completion of such activities and the deliverables for such activities, including:

**(i)** Compound API production and release testing for the conduct of the Phase 2 Activities, the Compound API stability program, other CMC Development activities, such as formulation and analytical development studies required for Phase 2 Clinical Trial and Phase 3 Clinical Trial use and for Marketing Approval;

**(ii)** Development of a Compound API synthesis process at commercial scale that is intended for inclusion in Marketing Authorization Applications;

**(iii)** Product formulation development of Product for use in the Phase 2 Clinical Trials and Phase 3 Clinical Trials that is intended for inclusion in Marketing Authorization Applications and for Commercialization;

**(iv)** Product production, and release testing, packaging and labeling for the Phase 2 Activities and Phase 3 Activities;

**(v)** Selection of Compound API and Product manufacturers for Phase 2 Activities and Phase 3 Activities and for Commercialization; and

**(vi)** A budget setting forth the estimated costs for such activities described in (i)-(v) above (the “CMC Budget”).

**(d) Amendments.** From time to time during the Development Term, either Party or a Subcommittee may submit proposed amendments to the Collaboration Plans to the JSC for review and approval. The JSC shall consider each such proposed amendment at its next scheduled meeting. If the JSC approves such proposed amendment in accordance with Section 3.1(a), the Clinical Development Plan or CMC Development Plan, as applicable, shall be deemed amended to reflect such amendment and such amended Clinical Development Plan or CMC Development Plan, as applicable, shall become effective and supersede the previous Clinical Development Plan or CMC Development Plan, as applicable, as of the date of such approval. If the JSC does not approve such proposed amendment, such matter shall be subject to escalation as described in Section 3.2(b).

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### 4.3 Collaboration CMC Activities.

(a) **Responsibility.** Subject to Section 4.3(b), each Party shall be responsible for conducting the Collaboration CMC Activities allocated to it in the CMC Development Plan. Each Party shall perform the CMC Collaboration Activities in accordance with the terms and conditions of this Agreement, in good scientific manner and in compliance with applicable Laws, including those relating to GMP. The JMC shall oversee the conduct of the Collaboration CMC Activities, and all decisions regarding the CMC Development Plan shall be discussed and reviewed by the JMC and approved by the JSC.

(b) **Diligence.** Each Party shall use Commercially Reasonable Efforts to conduct and complete the Collaboration CMC Activities allocated to it in the CMC Development Plan in accordance with the CMC Development Plan (including the timelines set forth therein). Each Party shall have day-to-day operational control over the Collaboration CMC Activities allocated to it in the CMC Development Plan.

### 4.4 Conduct of Activities during Development Term.

(a) **Sponsorship.** The Party responsible for conducting a Clinical Trial of a Product in accordance with this Article 4 and the Collaboration Plans (the "Conducting Party") shall be the sponsor of such Clinical Trial from a regulatory perspective (*e.g.* in the U.S., such Party will have the responsibilities of a sponsor as described in 21 C.F.R. 312).

(b) **Notifications.** The Conducting Party shall notify the other Party as soon as reasonably practicable in the event that the Conducting Party becomes aware of any of the following with respect to the applicable Clinical Trial:

- (i) protocol changes proposed to be made by the Conducting Party and/or that may be required by any Regulatory Authority;
- (ii) safety or technical issues;
- (iii) expected or actual material delay, or the occurrence of any event that may reasonably be expected to give rise to a material delay; or
- (iv) other material substantive issues.

Following receipt of notice of any such event, the Parties shall promptly meet to discuss the circumstance and the Conducting Party shall inform the other Party of its intended action plan to remedy (where possible) the issue and/or mitigate the delay risk to successful completion of the applicable Clinical Trial. In determining an action plan, the Conducting Party shall take the other Party's comments into consideration in good faith.

(c) **IRB.** The Conducting Party shall be responsible for obtaining any necessary approvals from institutional review boards (each, an "IRB") including, where

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applicable, obtaining approval of all Clinical Trial protocols, informed consents, investigator brochures, subject recruitment materials or plans, authorization of disclosure of confidential subject information, and any alterations to or waivers of the same, prior to commencement of any study. The Conducting Party shall not modify the protocol or the informed consent without the prior written agreement of the IRB.

**(d) Informed Consent and Patient Authorization.** The Conducting Party shall require the investigators for the Clinical Trial to obtain (i) an informed consent document, which shall have been approved by the IRB, signed by or on behalf of each human study subject prior to the subject's participation in the Clinical Trial; and (ii) a HIPAA authorization signed by or on behalf of each human study subject, as described in 45 C.F.R. Part 164 (or for sites outside of the United States, the foreign equivalent) (the "HIPAA Authorization"), which authorization shall contain such provisions as are necessary for the other Party to have access to patient data for purposes of conducting the Clinical Trial, analyzing the Clinical Trial results and for regulatory purposes with respect to the Products (*e.g.*, seeking Marketing Authorization of, or supporting other Regulatory Materials for, the Products).

**(e) Clinical Study Registration and Results Reporting.** The Conducting Party shall be responsible for registering such Clinical Trial in the appropriate clinical study registry and reporting Clinical Trial results as may be required under applicable Laws.

**(f) Samples.** The Conducting Party shall accept, to the extent permitted by applicable Laws, responsibility for the retention of documentation and storage of samples of Products according to applicable Laws (provided that, with respect to Janssen as the Conducting Party, the necessary documentation and samples have been transferred by Theravance in accordance with this Agreement).

**(g) Audits.** With respect to any facility or site of the Party (or its Third Party subcontractors) at which a Party (or its Third Party subcontractor) conducts any Development activities pursuant to this Agreement, the other Party shall have the right, at its own expense, upon reasonable written notice to such Party, and during normal business hours, to inspect such site and facility of such Party (or, in the case of a Third Party subcontractor, to accompany such Party to inspect such Third Party subcontractor site to the extent that such Party has a right to provide access for such inspection) and any records relating thereto once per year and also for cause, to verify such Party's compliance with applicable Laws in carrying out its obligations under this Agreement, including those relating to GLP, GCP, GMP, pharmacovigilance and safety reporting, and requirements for the protection of human subjects. If a Party's agreement with such subcontractor does not permit the other Party to attend inspections, the Party will use good faith efforts to facilitate a direct agreement between the applicable subcontractor and such other Party to permit such inspections. In the event that any such facility or site is found to be non-compliant with GLP, GCP, GMP, pharmacovigilance and safety reporting, or requirements for the protection of human subjects during such an audit, and such non-compliance relates to or impacts any Development activities hereunder, the audited Party shall submit to the auditing Party proposed Corrective and Preventative Actions ("CAPA") within thirty (30) days after the auditing Party provides notice of such non-compliance. The auditing Party shall have the right to review and comment on such CAPA, which comments the audited Party shall consider in good faith. The

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audited Party shall use Commercially Reasonable Efforts to implement such CAPA promptly after review and comment by the auditing Party. The results of any audit conducted pursuant to this Section 4.4(g) shall be the Confidential Information of the audited Party.

**(h) Manufacturing Site Audits.** In addition to its rights under Section 4.4(g), each Party shall have the right at its own expense, upon reasonable written notice to such Party, and during normal business hours, to conduct an audit of the other Party's (or its Third Party subcontractor's, to the extent such other Party has the right to grant the other Party access to such sites, *provided that*, if a Party's agreement with such subcontractor does not permit the other Party such access, the Party will use good faith efforts to facilitate a direct agreement between the applicable subcontractor and such other Party to permit such access) manufacturing sites where any Manufacturing activities with respect to the Product or Compound API are conducted hereunder by the other Party (the "Manufacturing Party") (or its Third Party subcontractors). Audits of a Third Party subcontractor site will be conducted accompanied by the Manufacturing Party. Following the completion of any such audit, the auditing Party may request the remediation of deficiencies that are not in compliance with GMP and identified during such audit, and the Manufacturing Party shall use Commercially Reasonable Efforts to remediate such deficiencies.

**(i) Audits by Regulatory Authorities.** Each Party shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility of the other Party or its Affiliates or subcontractors where Collaboration Activities or other activities with respect to the Product are conducted pursuant to this Agreement by or on behalf of such Party (each, an "Audited Site"). Such Party shall inform the other Party as promptly as practicable and in any event within forty-eight (48) hours of receiving notice of such a Regulatory Authority audit and shall provide reasonable updates to the other Party regarding the audit status. In the event that any Audited Site is found to be non-compliant with one or more of GLP, GCP, GMP, current standards for pharmacovigilance and safety reporting, or requirements related to the protection of human subjects, and such non-compliance relates to or impacts any Collaboration Activities, the audited Party shall submit to the other Party proposed CAPA within forty-five (45) days after the audited Party, its Affiliate, or its subcontractor receives notification of such non-compliance from the relevant Regulatory Authority. The other Party shall have the right to review and comment on such CAPA, which comments the audited Party shall consider in good faith. The audited Party shall use Commercially Reasonable Efforts to implement such CAPA.

**(j) Records; Data Requirements.**

**(i)** Each Party shall prepare and maintain, and shall cause its Affiliates and Third Party subcontractors to prepare and maintain, complete and accurate written records, accounts, notes, reports and data with respect to the Collaboration Activities (the "Collaboration Records"), in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in conformity with applicable Laws and such Party's standard practices, which Collaboration Records shall reflect all work done and results achieved in connection with the Collaboration Activities. Each Party shall retain, and cause its Affiliates and Third Party subcontractors to retain, the Collaboration Records for at least three (3) years from the completion of the Collaboration Activities or such longer period as may be required by applicable Laws.

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**(ii)** Each Party shall comply with Janssen's data policies set forth on Exhibit H with regard to Collaboration Records.

**(k) Reports.** During the Development Term:

**(i)** each Party shall provide quarterly updates on its progress with respect to the conduct of the Phase 2 Activities and Phase 3 Activities, and a summary of the data and results from such activities, at each meeting of the JSC;

**(ii)** each Party shall provide quarterly updates on its progress with respect to the conduct of Collaboration CMC Activities, and a summary of the data and results from such activities, at each meeting of the JMC; and

**(iii)** in addition to any such reports made to the JSC or JMC, each Party shall make its employees and consultants available for an in-person or telephonic meeting with the other Party at least once every Calendar Quarter to discuss its progress with respect to the conduct of the Collaboration Activities.

**(l) Material Safety Issues.** If, during the Development Term, either Party determines that there is a Material Safety Issue, such Party shall promptly notify the other Party and the JSC shall promptly meet to discuss such Material Safety Issue and to seek to approve an appropriate course of action to address such Material Safety Issue (which may include delaying, modifying, suspending or terminating one or more of the Collaboration Activities). During the pendency of such discussion, each Party may suspend or delay any Collaboration Activity allocated to it under the Collaboration Plans to the extent such activity is affected by such Material Safety Issue. If the JSC approves a course of action to address such Material Safety Issue, then the Parties shall thereafter take all reasonable actions necessary to implement such course of action. If the JSC does not approve a course of action to address such Material Safety Issue within twenty one (21) days after becoming aware of such Material Safety Issue, then either Party may refer such matter to the Executive Officers for discussion and attempted resolution. If the Executive Officers approve a course of action to address such Material Safety Issue, then the Parties shall thereafter take all actions necessary to implement such course of action. If the Executive Officers do not approve a course of action to address such Material Safety Issue within twenty one (21) days after the matter is referred to them, then, the matter shall be considered a Deadlocked Matter in accordance with Section 3.2(b); provided, however, that the Party with final decision-making authority may not exercise such authority to require the other Party to commence or continue any Collaboration Activity if the other Party determines, in good faith, that such Collaboration Activity should not be commenced or continued due to such Material Safety Issue and in such instance the Party with final decision-making authority would have the right to authorize a clinical research organization to conduct the particular activity on its own behalf.

**(m) Transition and Technology Transfer.**

**(i)** Prior to the Opt-In Date, Janssen may perform technology transfer activities, the cost of which shall be allocated in accordance with Section 6.3(a).

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**(ii)** To facilitate an orderly transition of the Development and Manufacture of the Compounds and Products from Theravance to Janssen:

1. promptly following the Opt-In Date [\*\*\*] from the Opt-In Date, Theravance shall transfer to Janssen, and shall assign and hereby assigns (effective upon such transfer) to Janssen all its right, title and interest in, to and under, all INDs and other clinical trial agreements (subject to obtaining any required consents), safety databases and other Regulatory Materials (excluding any audit reports) that are specific to the Initial Compounds and Initial Products for Crohn's disease and then held by Theravance or its Affiliates; and

2. upon Janssen's request after the Opt-In Date, Theravance shall, and shall cause its Third Party manufacturer(s) (subject to the terms of any applicable agreement(s) with such Third Party manufacturer(s)), to transfer existing Manufacturing processes for, and existing inventories of, the Compound API and Products to Janssen (or its designee) and to provide reasonable technical assistance to Janssen (or its designee) in establishing Manufacturing processes for the Compounds and Products, pursuant to a mutually agreed CMC transfer plan and in accordance with Section 6.3, with Janssen to bear sixty-seven percent (67%) of such costs, and Theravance to bear thirty-three percent (33%).

**(iii)** After the Opt-In Date, Theravance will transfer any other Theravance Know-How reasonably requested by Janssen (e.g., assays) in order to Develop and Manufacture the Compounds and Products. Upon Janssen's request during the Term after the Opt-In Date, Theravance shall promptly provide to Janssen (a) complete sets of any preclinical or clinical data generated by or on behalf of Theravance with respect to any Compound or Product, (b) raw data tables with respect to the data described in clause (a), (c) CMC data or information generated by or on behalf of Theravance with respect to any Compound or Product or (d) any other Theravance Know-How that is necessary or specifically useful for the Development, Manufacture or Commercialization of Compounds and Products, in each case ((a) - (d)), to the extent that such information was not previously provided by Theravance to Janssen.

**(iv)** After the Opt-In Date, Janssen shall have the sole right and authority to Develop Compounds and Products in the Field in the Territory.

#### **4.5 Combination Studies.**

**(a)** [\*\*\*]. For the avoidance of doubt, [\*\*\*]. [\*\*\*]. If the Parties cannot reach agreement with respect to the terms, the Parties shall refer such dispute to a neutral third party arbitrator reasonably agreeable to both Parties for determination.

**(b)** Notwithstanding Section 4.5(a), Janssen may conduct studies or research to develop a Combination Product by utilizing a Compound in combination with another compound according to the terms of this Section 4.5(b), and Theravance hereby grants a non-exclusive license

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to Janssen under Theravance IP for purposes of conducting such Combination Product studies, research and development during the Term.

(i) Prior to the Opt-In Date and subject to Section 2.3(c), Janssen shall not conduct any studies or research to develop a Combination Product, unless mutually agreed by the Parties.

(ii) Following the Opt-In Date, Janssen will provide advance notice to Theravance of any such non-clinical studies or research and shall promptly disclose the results of such studies and research to Theravance (subject to any applicable confidentiality obligations imposed on Janssen).

(iii) Following the Opt-In Date, Janssen will submit any proposed Combination Product Clinical Trials to the JSC for review and approval. Janssen will promptly disclose the results of any such approved Combination Product Clinical Trials to Theravance (subject to any applicable confidentiality obligations imposed on Janssen) and such results shall be discussed at the JSC.

(iv) Ownership of Patent Rights and other intellectual property developed pursuant to this Section 4.5 ("Combination Product IP") shall be in accordance with the terms of Section 7.1. Except to the extent that such intellectual property constitutes Theravance IP subject to the Commercial License, each such Party shall, and hereby does, grant the other a nonexclusive license to Combination Product IP, solely for purposes of conducting non-commercial, internal research activities in furtherance of efforts to identify new therapeutic and diagnostic agents.

**4.6 Development Records.** Each Party shall maintain complete, current and accurate records of all Development activities conducted by it hereunder, and all data and information resulting from such activities. Such records shall accurately and completely reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes.

**4.7 Development Reports.** Each Party shall keep the JDC reasonably informed of the Development activities performed by such Party under this Agreement. Without limiting the foregoing, at each regularly scheduled JDC meeting, each Party shall provide the JDC with a summary report of the Development or Manufacturing activities performed by it hereunder since the last JDC meeting and the results thereof. The JDC shall discuss the progress and results of the Parties' Development or Manufacturing activity hereunder, and each Party shall promptly respond to the other Party's reasonable questions or requests for additional information relating to such Development or Manufacturing.

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#### 4.8 Manufacture.

(a) **Prior to the Opt-In Date.** Theravance shall be responsible, at its cost, for the Manufacturing and supply of all Products and Compound API required for the Initial Trials of the Initial Product and the Pre-Opt-In Phase 3 Activities initiated pursuant to the Collaboration Plans during the Opt-In Period, in accordance with the Collaboration Plans; provided that the costs of Manufacturing Product for the Pre-Opt-In Phase 3 Activities will be subject to Section 6.3(a). Theravance will conduct, and will use Diligent Efforts to ensure that its Affiliates and any Third Party manufacturer(s) conduct, such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with applicable Laws, including those relating to GMP.

(b) **After the Opt-In Date.** Except as set forth in this Section 4.8 or as otherwise agreed by the Parties and included in the Collaboration Plans, after Opt-In Date, Janssen shall have the sole responsibility to Manufacture clinical and commercial supplies of Compounds and Products. Janssen will conduct, and will use Diligent Efforts to ensure that its Affiliates and any Third Party manufacturer conducts, such Manufacturing activities in accordance with the terms and conditions of this Agreement and in compliance with applicable Laws, including those relating to GMP.

#### 4.9 Regulatory Matters.

(a) **Prior to the Opt-In Date.** Prior to the Opt-In Date, Theravance shall be solely responsible for, and have sole authority with respect to, all regulatory matters with respect to the Products, and shall have the right to file, obtain and maintain, in its own name, all Regulatory Materials with respect to the Products; *provided, however,* that upon Theravance's request, Janssen may support regulatory activities in good faith and at its discretion with respect to the Product in the Territory prior to the Opt-In Date, including determination of regulatory strategy, review of Regulatory Materials, and attending meeting with Regulatory Authorities. Theravance shall have the sole responsibility for, and sole authority with respect to, communications with any Regulatory Authority regarding such Regulatory Materials; *provided* that Janssen shall have the right to attend and participate in all material meetings, conferences and discussions between Theravance and any Regulatory Authority to the extent pertaining to the Products. Theravance shall provide Janssen with reasonable advance notice of all such meetings, conferences and discussions and advance copies of all related documents and other relevant information relating to such meetings, conferences and discussions. Theravance shall provide Janssen with advance drafts of any material Regulatory Materials with respect to the Products that Theravance plans to submit to any Regulatory Authority reasonably in advance of filing where practicable for Janssen's review and comment. Janssen may provide comments regarding such Regulatory Materials prior to Theravance's submission of such materials to a Regulatory Authority, and Theravance shall use reasonable efforts to incorporate any reasonable comments received from Janssen prior to submission of such materials to any Regulatory Authority; *provided* that Theravance shall not be obligated to provide Janssen with more than ten (10) days (or such shorter period required by Regulatory Authorities) to review such Regulatory Materials. In addition, in the event Theravance is notified of any material regulatory or other inquiries from Governmental Entities with respect

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to the Products prior to the Opt-In Date, Theravance shall promptly notify Janssen of such inquiries.

**(b) After the Opt-In Date.** After the Opt-In Date, Janssen shall be solely responsible for, and have sole authority with respect to, seeking, obtaining and maintaining Marketing Approvals for the Products in the Field in the Territory and to conduct all related regulatory matters, including communications with any Regulatory Authority relating to the Products; *provided* that Theravance shall have the right to attend, in an observer capacity all material meetings, between Janssen and any Regulatory Authority pertaining to the Products; and provided further that Theravance may conduct the Phase 2/3 UC Study in accordance with the Collaboration Plans and manage interactions with Regulatory Authorities as sponsor of such study. Janssen shall provide Theravance with reasonable advance notice of all such meetings. Janssen will keep Theravance reasonably informed with respect to correspondence and meetings regarding the Products with Regulatory Authorities, and shall provide Theravance with copies of material Regulatory Materials and correspondence with respect thereto, submitted to or received from the FDA. Upon Janssen's request and at Janssen's expense, Theravance shall provide reasonable assistance as necessary for Janssen to file applications for Marketing Approval for the Products and obtain and maintain Marketing Approvals with respect to the Products as agreed in the then-current Collaboration Plan.

**(c) Regulatory Inspection.**

**(i)** Theravance shall promptly (and in any event within one (1) Business Day of becoming aware thereof) notify Janssen of any Regulatory Authority inspections or audits of Theravance's or its Affiliates' facilities relating to any Product or related activities with respect to the Development, or those related activities under the Collaboration Plans. Janssen shall have the right to be present at any such inspections, if permitted by such Regulatory Authority, and shall have the opportunity to provide, review and comment on any responses that may be required. Theravance shall provide Janssen with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection. In addition to such obligations with respect to Regulatory Authority inspections, Theravance shall promptly (and in any event within one (1) Business Day following receipt thereof) notify Janssen of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory Authority, that may materially affect the Development, Manufacturing, Commercialization or regulatory status of Products.

**(ii)** Janssen shall promptly (and in any event within one (1) Business Day of becoming aware thereof) notify Theravance of any Regulatory Authority inspections or audits relating to any Product or related activities under the Collaboration Plans or the Commercialization Plan. Janssen shall provide Theravance with copies of all materials, correspondence, statements, forms and records received or generated pursuant to any such inspection. In addition to such obligations with respect to Regulatory Authority inspections, Janssen shall promptly (and in any event within one (1) Business Day following receipt thereof) notify Theravance of any information it receives regarding any threatened or pending action or communication by or from any Third Party, including a Regulatory

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Authority, that may materially affect the Development, Manufacturing, Commercialization or regulatory status of Products.

**4.10 Subcontracts.** Each Party may perform its Development, Manufacturing and Commercialization obligations under this Agreement through one or more subcontractors, *provided* that (a) the subcontracting Party shall remain responsible for the work delegated to, and payment to (subject to Section 6.3), its subcontractors to the same extent it would if it had done such work itself and, (b) to the extent the subcontracting Party is a Third Party, the subcontracting Party shall enter into a written agreement with the subcontractor that is consistent with this Agreement, including provisions relating to confidentiality and intellectual property rights that are at least as restrictive as those in this Agreement.

## ARTICLE 5 COMMERCIALIZATION

**5.1 Commercialization Responsibilities.** Janssen will have the exclusive right to conduct (subject to Section 5.2), and will have sole decision-making authority with respect to all aspects of the Commercialization of Compounds and Products in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan; (b) marketing and promotion (including Detailing); (c) booking sales and distribution and performance of related services; (d) handling all aspects of order processing, invoicing and collection, inventory and receivables; (e) publications; (f) providing customer support, including handling medical queries, and performing other related functions; (g) the review and approval of all promotional materials for compliance with applicable Law, including submission, where appropriate, to the applicable Regulatory Authority and (h) conforming its practices and procedures in all material respects to applicable Law relating to the marketing, detailing and promotion of the Products in the Field in the Territory. Janssen shall use Commercially Reasonable Efforts to obtain Marketing Approval for the Product and Commercialize a Product in each of the [\*\*\*] following receipt of Marketing Approval of such Product in the applicable country. Promptly after the Opt-In Date and thereafter during the Term on an annual basis, [\*\*\*] may be added to the Development Plan for approval by the JSC.

### **5.2 Theravance Commercialization Option.**

**(a) Grant of Commercialization Option.** Theravance will have the option, on a Product-by-Product basis (but, for the avoidance of doubt, excluding Combination Products), to execute [\*\*\*] of certain Commercialization activities, including Detailing and other direct sales activities, and Medical Affairs activities, such as medical science liaisons, publications, KOL relationship management and Phase 4 Clinical Trial participation, for each Product in the U.S. (“Commercialization Option”).

**(b) Exercise of Commercialization Option.** To exercise the Commercialization Option with respect to a Product, Theravance shall provide notice to Janssen

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no later than [\*\*\*] the date on which the first dose is administered to the last patient enrolled in the pivotal Phase 3 Clinical Trials for UC. Together with such notice, Theravance shall provide to Janssen evidence of Theravance's capability to perform the specified commercialization activities for such Product (and provide an estimate of anticipated expenses related to such activities), or Theravance's plans to build or acquire such capabilities. Theravance shall provide Janssen with an opportunity to review Theravance's plan with respect to Commercialization, including by confirming that Theravance has the appropriate staffing, resources, systems and budget to carry out such plan. If Theravance does not exercise the Commercialization Option with respect to the first Product for which Janssen delivers a Commercialization Plan pursuant to this Section 5.2(b), then the Commercialization Option shall not apply to any future Products. If Theravance exercises the Commercialization Option with respect to [\*\*\*], Theravance shall [\*\*\*] of the aggregate amount of Commercialization activities for all such Products [\*\*\*] of the aggregate amount of Commercialization activities for any such Product. Effective upon Theravance's exercise of the Commercialization Option, subject to the terms and conditions of this Agreement, Janssen shall grant, and hereby grants, to Theravance a non-exclusive license under Janssen's Sole Inventions, including any Janssen Sole Patent Rights, for purposes of conducting such Commercialization activities as are assigned to Theravance in the Commercialization Plan or the Commercialization Agreement.

**(c) Commercialization Agreement.** Within [\*\*\*] of exercising the Commercialization Option for a Product, Theravance and Janssen will negotiate and enter into a commercialization agreement for such Product consistent with the provisions of this Agreement, the key commercialization terms set forth in this Section 5.2 and such other terms as the Parties may agree and as are customary in an agreement of that type to govern the Parties' joint Commercialization of the Products in the U.S. (the "Commercialization Agreement"). Theravance shall have the right to designate an Affiliate incorporated in the U.S. to undertake the rights and obligations otherwise attributable to Theravance under the Commercialization Agreement with Janssen's prior written consent, not to be unreasonably withheld; provided that such consent is hereby provided with respect to Theravance Biopharma US, Inc., so long as it remains a U.S. entity and an Affiliate of Theravance.

**(d) Authority of the Parties.** Notwithstanding the Commercialization Option, Janssen shall maintain sole authority with respect to (i) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of Products; (ii) booking sales and distribution of the Product and performance of related services; (iii) handling all aspects of order processing, invoicing and collection, inventory and receivables for the Product; (iv) providing customer support, including handling medical queries, and performing other related functions; and (v) Manufacturing of Products for commercial use throughout the Territory. Additionally, subject to Section 5.2(b) and as otherwise agreed to by the Parties, Janssen shall [\*\*\*], Janssen shall conduct the activities in Sections 5.2 and 5.3 for the U.S. in consultation with Theravance, including through the JSC.

**(e) Terms of Commercialization Agreement.** The Parties shall negotiate in good faith to include in the Commercialization Agreement such usual and customary terms as are typically found within co-promotion agreements, as well as provisions with respect to the co-

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detailing in the U.S. of each Product for which Theravance exercises the Commercialization Option, including the terms set forth below in this Section 5.2(e).

(i) [\*\*\*].

(ii) The Commercialization Agreement would be subject to the same restrictions on assignment set forth in Section 13.7 of this Agreement.

(iii) [\*\*\*].

(iv) A working group or other administrative body would be established by the Parties to serve solely as an information-sharing body with respect to each Party's Detailing and other Commercialization activities in the United States with respect to the Products, and not as a decision-making body.

(v) Theravance would contribute a percentage determined by the CWG of Janssen's planned Details for each such Product in the U.S. for each calendar year [\*\*\*], as set forth in Janssen's call plan for such calendar year. Theravance would employ a number of sales representatives sufficient to provide the agreed percentage of Details for each such Product in the U.S. for each calendar year.

(vi) Following consultation through the CWG, Janssen would have the right to allocate the planned Details for each such Product in the U.S. for each calendar year between the Parties. The Parties would coordinate their Detailing activities for such Products in the U.S. in accordance with mutually agreed procedures.

(vii) Janssen would include the Detail Rate as Allowable Expense as part of the Profit (Loss) calculation for the Product in the U.S. The Detail Rate shall be determined by the CWG and commensurate with the fair market value of such activities as provided by Third Party contract sales organizations.

(viii) All Theravance sales representatives who would Detail any Product in the U.S. [\*\*\*].

(ix) Theravance would compensate its sales representatives who detail each such Product in the U.S. [\*\*\*].

(x) Each sales representative who details any Product in the U.S. on behalf of Theravance [\*\*\*].

(xi) Theravance's sales representatives performing Details of a Product in the U.S. would be required to comply with applicable Laws and all of Janssen's reasonable instructions, quality standards, policies and guidelines which relate to the Commercialization of such Product and of which Theravance has been given reasonable written notice. Theravance would establish a compliance program and appoint a compliance officer to ensure that Theravance's detailing of such Product is in compliance with applicable Laws and such Janssen instructions, quality standards, policies and guidelines.

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Janssen would have the right to audit Theravance's records regarding performance under the Commercialization Agreement, solely for the purpose of determining Theravance's compliance with the Commercialization Agreement.

(xii) [\*\*\*].

**5.3 Commercialization Plan.** On an annual basis, Janssen will prepare a plan for the Commercialization of the Products in the Field in the Territory ("Commercialization Plan") which will address key activities intended to achieve the successful Commercialization of Products in the Field in the United States during the following [\*\*\*] and the Commercial Budget associated therewith. The Commercialization Plan will contain at least the depth and detail that are typical for Janssen's internal commercial plans for similar products (acknowledging decreasing depth and detail for latter portion of the [\*\*\*] period), and shall set forth the number of sales representatives that Janssen anticipates requiring to complete the Details in such Commercialization Plan as well as key activities for the global Product brand that are included in Allowable Expenses. In accordance with Section 3.5, the initial Commercialization Plan shall be prepared and submitted to the CWG no later than [\*\*\*] after the filing of the New Drug Application (as defined in the FD&C Act) for the Product with the FDA, and the Commercialization Plan shall be updated by Janssen annually thereafter, and submitted to the CWG.

**5.4 Theravance Commercial Diligence.** If Theravance enters into a Commercialization Agreement with respect to a Product, Theravance shall use Commercially Reasonable Efforts to Commercialize such Product in the United States, in each case, in accordance with the terms of this Article 5. Further, the Parties shall conduct their Commercialization activities with respect to the Product(s) in the Field in the Territory in accordance with applicable Laws and, with respect to the United States, the then-current Commercialization Plan.

**5.5 Transparency Reporting.** Janssen, and, in the event it exercises the Commercialization Option, Theravance, shall each be responsible for tracking and reporting transfers of value initiated and controlled by such Party and its Affiliates and its and its Affiliates' employees, contractors, and agents pursuant to the requirements of the marketing reporting laws or research expense reporting laws of any Governmental Authority in the Territory, including Section 6002 of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act."

#### **5.6 Labeling.**

**(a) U.S.** For any period that Theravance exercises its Commercialization Option with respect to a Product, labeling for the Product in the Field in the U.S. shall include (unless prohibited by Law) the Janssen Housemark and the Theravance Housemark, each of which shall be given substantially equal exposure and prominence on such materials and, without limiting

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the foregoing agreed exposure and prominence, be in accordance with Janssen's master branding guidelines. In the event that Theravance does not exercise its Commercialization Option with respect to a Product, or ceases Commercializing such Product in the Field in the U.S., such Labeling shall include a reference (unless prohibited by Law) to the license from Theravance for the Product (for example, by stating "Licensed from Theravance Biopharma Ireland Limited") in the Labeling for the Products.

**(b) Outside the U.S.** All Labeling (other than promotional materials) for use with the Products in the Field outside the U.S. shall include a reference (unless prohibited by Law) to the license from Theravance for the Product (for example, by stating "Licensed from Theravance Biopharma Ireland Limited") in the Labeling for the Products.

## ARTICLE 6 COMPENSATION

**6.1 Upfront Payments.** Within [\*\*\*] after the Effective Date and receipt of an invoice from Theravance, Janssen shall pay to Theravance a one-time, non-refundable, non-creditable upfront payment of one hundred million Dollars (\$100,000,000).

**6.2 Opt-In Exercise Fee.** Except as otherwise provided in Section 2.5(b), upon Janssen's exercise of the Option and the receipt of all necessary Clearances as provided in Section 2.2, Janssen shall pay to Theravance a one-time, non-refundable, non-creditable opt-in exercise fee of two hundred million Dollars (\$200,000,000) (the "Opt-In Exercise Fee") on the Option Completion Date, as set forth in Section 2.2.

### **6.3 Cost Sharing.**

**(a)** [\*\*\*]. Notwithstanding the foregoing, Theravance shall be responsible for sixty seven percent (67%) and Janssen shall be responsible, and reimburse Theravance on a Calendar Quarterly basis, for thirty three percent (33%) of the FTE Costs and Out-of-Pocket Costs associated with Pre-Opt-In Phase 3 Activities. In the event that Janssen exercises the Option, Janssen shall reimburse Theravance for an amount equal to an additional [\*\*\*] that are incurred by Theravance prior to the Opt-In Date in accordance with Section 6.9. [\*\*\*]. The initial budget for activities prior to the Opt-In Date is included as Exhibit O.

**(b)** After the Opt-In Date, Theravance, or its Affiliate, shall be responsible and shall reimburse Janssen on a Calendar Quarterly basis in accordance with Section 6.9, for thirty three percent (33%), and Janssen shall be responsible for sixty seven percent (67%) of all Development Costs incurred by the Parties in accordance with the Development Budget, including Phase 3 Development Costs, Phase 3 CMC Development Costs and costs of the transfer of Manufacturing to an internal or external manufacturing site, including regulatory and filing fees (with respect to a Party, such percentage is referred to as its "Specified Percentage"), provided that Janssen shall be responsible for [\*\*\*] of all Development Costs incurred in conducting Clinical

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Trials solely for purposes of addressing specific requirements provided by a Regulatory Authority of a specific jurisdiction(s) outside the U.S.

(c) Notwithstanding anything in this Section 6.3 to the contrary, [\*\*\*]. If Theravance's aggregate payments pursuant to Section 6.3(a) for Development Costs incurred between the Opt-In Date and First Commercial Sale would exceed [\*\*\*], then Theravance may, in its sole discretion, defer payment of all or a portion of its Specified Percentage of any additional Development Costs in excess of such amount incurred during such period ("Deferrable Costs") as provided below; [\*\*\*]. Deferrable Costs shall accrue interest at the Applicable Rate, compounded annually.

(i) Janssen may recoup any Deferrable Costs actually deferred by Theravance, and any interest accrued thereon, by crediting such amount against any monies that Janssen is subsequently obligated to pay Theravance under this Agreement, including Theravance's share of Profit (Losses) for any Product and any milestones or royalties, as applicable; provided that Janssen shall allocate such recoupment such that amounts owed to Theravance hereunder during any given Calendar Quarter are not reduced by more than [\*\*\*], and in such circumstance shall apply any portion of the recoupment that it did not collect because of such reduction below [\*\*\*] to one or more subsequent Calendar Quarters in accordance with the terms of this provision; provided further that Theravance shall, in any case, repay any Deferrable Costs actually deferred by Theravance and accrued interest thereon within [\*\*\*] after launch of the Initial Product in the United States.

(ii) In the event a First Commercial Sale does not occur or Janssen is otherwise unable to recoup all Deferrable Costs and accrued interest thereon prior to a determination to cease selling the Product, Theravance shall repay all Deferrable Costs to Janssen [\*\*\*].

(iii) [\*\*\*].

(d) Development Costs will not be included in Allowable Expenses for purposes of calculating Profit (Loss) in accordance with Exhibit M, and any amounts included in Allowable Expenses will not be included in Development Costs (and in any case no item of expense shall be counted more than once in Development Costs or Allowable Expenses).

(e) Solely with respect to Phase 3 Development Costs, but subject always to the cap set forth in Section 6.3(c):

(i) in the event a Party performing Phase 3 Activities for which it is responsible under the Clinical Development Plan incurs more than [\*\*\*] of aggregate Phase 3 Development Costs budgeted for such activities, [\*\*\*]; and

(ii) in the event a Party performing Collaboration CMC Activities for the Phase 3 Activities for which it is responsible under the CMC Development

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Plan incurs more than [\*\*\*] of aggregate Phase 3 CMC Development Costs budgeted for such activities in the Phase 3 CMC Development Budget, [\*\*\*].

(f) In the event that a dispute arises with respect to the amounts set forth in a report or invoice delivered under this Section 6.3, and the Parties are unable to resolve such dispute within twenty (20) Business Days after such dispute is first raised, the Parties shall follow the dispute resolution process as described in Section 12.1.

(g) The audit rights set forth in Section 6.13 shall apply to any payment made pursuant to this Section 6.3.

(h) Neither Party will double charge the other Party for any FTE costs or other costs or expenses under this Section 6.3.

**6.4 Development Milestone Payments.** Janssen shall notify Theravance [\*\*\*] after the achievement by Janssen or its Affiliates or sublicensees of the development milestone events set forth in the table below. Thereafter, Theravance shall invoice Janssen for the corresponding milestone payment set forth in the table below, and Janssen shall pay each such invoice within [\*\*\*] after receipt thereof. Each payment set forth in this Section 6.4 shall be non-refundable and non-creditable.

| <b>Development Milestone Event</b> | <b>Milestone Payment for First Primary Indication</b> | <b>Milestone Payment for Other Primary Indication</b> | <b>Milestone Payment for Other Indication</b> |
|------------------------------------|---|---|---|
| [***] (“ <u>Milestone 1</u> ”)     | [***]   | [***]   | [***]   |
| [***] (“ <u>Milestone 2</u> ”)     | [***]   | [***]   | [***]   |

[\*\*\*]. It shall not be necessary for the same Product to achieve the applicable milestone event in each of the three indication categories. Accordingly, the maximum amount payable by Janssen pursuant to this Section 6.4 is [\*\*\*].

**6.5 Sales Milestones.** Janssen shall notify Theravance within [\*\*\*] after the achievement by Janssen or its Affiliates or sublicensees of the sales milestone events set forth in the table below. Thereafter, Theravance shall invoice Janssen for the corresponding milestone payment set forth in the table below, and Janssen shall pay each such invoice within [\*\*\*] after receipt thereof. Each payment set forth in this Section 6.5 shall be [\*\*\*]. Each such sales milestone payment shall be

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\*\*\*]. For clarity, the milestone payments set forth in the table below \*\*\*] in accordance with this Section 6.5.

| Sales Milestone Event  | Sales Milestone Payment |
|--|-------------------------|
| Upon the first occasion that annual aggregate Net Sales of Products ***] in a calendar year exceeds ***] | ***]                    |
| Upon the first occasion that annual aggregate Net Sales of Products ***] in a calendar year exceeds ***] | ***]                    |
| Upon the first occasion that annual aggregate Net Sales of Products ***] in a calendar year exceeds ***] | ***]                    |

**6.6 Profit (Loss) Share in the United States.** During the Profit (Loss) Term, the Parties shall share Profits (Losses) from the sale of the Products in the Field in the U.S. as follows: sixty seven percent (67%) to Janssen and thirty-three percent (33%) to Theravance. The sharing of Profits (Losses) set forth in this Section 6.6 shall be reported, calculated and paid in accordance with Section 6.9 below. Theravance shall have the right to assign its rights and obligations under this Section 6.6 to an Affiliate, subject to the same restrictions on assignment set forth in Section 13.7.

**6.7 Profit (Loss) Term.** The Parties shall share Profits (Losses) in accordance with Section 6.6 for so long as the Product is being Developed and Commercialized in the United States under this Agreement (the “Profit (Loss) Term”), provided that the Profit (Loss) Term shall expire in the event that annual Net Sales of the Product are \*\*\*].

**6.8 Royalties Outside the U.S.**

(a) **Royalty Rates.** Subject to this Section 6.8, Janssen shall pay to Theravance royalties on aggregate annual Net Sales of Products outside the United States, as calculated by multiplying the applicable royalty rate by the corresponding portion of Net Sales of Products outside the United States in each calendar year as set forth in the table below.

| Royalties on Aggregate Net Sales Outside the United States  |      |
|---|------|
| For that portion of annual aggregate Net Sales of Products outside the United States less than or equal to ***] Dollars ***]                                    | ***] |
| For that portion of annual aggregate Net Sales of Products outside the United States greater than ***] Dollars ***] and less than or equal to ***] Dollars ***] | ***] |
| For that portion of annual aggregate Net Sales of Products outside the United States greater than ***] Dollars ***]   | ***] |

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By way of example, if annual Net Sales of a Product outside the U.S. during such calendar year were \$1.2 billion, the royalties due with respect to such Product would equal [\*\*\*].

(b) **Royalty Term.** Royalties shall be paid under this Section 6.8, on a Product-by-Product and country-by-country basis, [\*\*\*].

(c) **Royalty Reduction.** On a country-by-country and Product-by-Product basis, [\*\*\*].

(d) **Third Party Blocking Intellectual Property.** If Janssen obtains a license from a Third Party under any Third Party Blocking Intellectual Property Rights after the Opt-In Date, [\*\*\*].

(e) **Limit on Royalty Reductions During the Royalty Term.** In no event shall the royalties paid to Theravance with respect to a particular Product in a particular country in a particular Calendar Quarter during the Royalty Term [\*\*\*].

## 6.9 Reports and Payments.

(a) On or before the [\*\*\*] of each Calendar Year, each Party will provide a written report to the other Party setting forth a rolling, non-binding annual forecast for Development Costs anticipated to be incurred by or on behalf of such Party or any of its Affiliates and the Allowable Expenses anticipated to be incurred by or on behalf of such Party or any of its Affiliates during the current Calendar Year broken out on a quarterly basis. In addition, approximately [\*\*\*] days after the end of each Calendar Quarter, each Party will submit to the other Party a report setting for its then-current estimate of (i) (with respect to each Party's report) Development Costs and Allowable Expenses incurred by the reporting Party and (ii) (with respect to Janssen's report) Net Sales by or on behalf of Janssen and royalties owed to Theravance, in each case during such Calendar Quarter.

(b) Within [\*\*\*] after the end of each Calendar Quarter after the Opt-In Date, Theravance shall submit to Janssen a written report setting forth in reasonable detail for such Calendar Quarter (i) Development Costs and (ii) Allowable Expenses incurred by Theravance. Within [\*\*\*] after the end of each Calendar Quarter after the Opt-In Date, Janssen shall submit to Theravance a written report (each, a "Quarterly Report") setting forth in reasonable detail for such Calendar Quarter (i) gross sales of Products in the Territory by Janssen, its Affiliates and sublicensees, in the aggregate and on a regional basis, (ii) Net Sales in the Territory, in the aggregate and on a regional basis, (iii) royalties owed to Theravance on Net Sales outside the United States, (iv) Development Costs, (v) Allowable Expenses for Products sold in the U.S., (vi) technology transfer, (vii) Profits (Losses) and each Party's share thereof and (viii) the amounts due to or from the relevant Party, as well as the computation of each of the foregoing.

(c) Following receipt of such report, each Party shall reasonably cooperate to provide additional information as necessary to permit calculation and reconciliation for the

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applicable Calendar Quarter, and in a reasonable time in advance of applicable payments to accomplish the sharing of Profit (Loss) for the applicable Calendar Quarter.

(d) Subject to Section 6.10 below, within [\*\*\*] following the end of each Calendar Quarter, the Parties shall make any reconciling payments necessary to effect the royalties owed to Theravance pursuant to Section 6.7, the sharing of Development Costs set forth in Section 6.3, and Profits (Losses) set forth in Section 6.6 for such Calendar Quarter. For clarity, if the amount of the Profits (Loss) is negative with respect to any Calendar Quarter, the Parties will share such negative Profit (Loss) in accordance with Section 6.6, and the under-paying Party will make any necessary payments to the other Party.

(e) [\*\*\*].

(f) The reports required by this Section 6.9 shall be the reporting Party's Confidential Information subject to the protections of Article 10 of this Agreement.

**6.10 Payment Disputes.** In the event that the Finance Working Group cannot resolve a dispute regarding any amount reported by a Party or any amount owed under Section 6.8 above within [\*\*\*], the JSC shall promptly meet and negotiate in good faith a resolution to such dispute. In the event that the JSC is unable to resolve such dispute within [\*\*\*] after notice by the disputing Party, the Parties will follow the dispute resolution procedures set forth in Section 12.1.

**6.11 Foreign Exchange.** If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are received or paid in a currency other than Dollars, then such amounts shall be converted to their Dollar equivalent as follows:

(a) Janssen will notify Theravance in writing of Janssen's Currency Hedge Rate for a given Calendar Year in advance of such Calendar Year, within 10 Business Days after the Currency Hedge Rate(s) are available from its Affiliates, which is customarily at the end of November of the preceding Calendar Year.

(b) The Currency Hedge Rate(s) as provided in the notice to Theravance will remain constant throughout the applicable Calendar Year and until Janssen notifies Theravance in writing of an updated Currency Hedge Rate in accordance with Section 6.11(a) above, and the Parties shall use such Currency Hedge Rate(s) to convert non-Dollar amounts to Dollars for the purpose of calculating Profit (Loss) for, and Development Costs incurred during, each Calendar Quarter in the applicable Calendar Year.

**6.12 Manner and Place of Payment.** All payments owed by Janssen under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Theravance. All payments owed by Theravance under this Agreement

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shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Janssen.

**6.13 Records; Audits.** Each Party shall keep, and shall cause its Affiliates and sublicensees to keep, such accurate and complete records of (i) for Janssen, Development Costs and Net Sales, for Products sold in the United States: Profits (Losses), Development Costs and Allowable Expenses, and for Products sold outside the United States: Net Sales, royalties, and the calculations thereof; and (ii) for Theravance, Development Costs and, for Products sold in the United States, Allowable Expenses, and the calculations thereof, in each case as are necessary to determine the amounts due to the other Party under this Agreement and such records shall be retained by each Party or any of its Affiliates or sublicensees (in such capacity, the "Recording Party") for at least the three (3) calendar years subsequent to the calendar year to which such costs, expenses or Net Sales, and Profits (Losses) relate. During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of the other Party, by an independent certified public accountant, or the local equivalent, appointed by the other Party and reasonably acceptable to the Recording Party for the sole purpose of verifying the accuracy of the Recording Party's accounting reports and payments made or to be made pursuant to this Agreement; *provided, however* that such audits may not be performed by the other Party more than once per calendar year. Such accountants shall be instructed not to reveal to the auditing Party the details of its review, except for (i) such information as is required to be disclosed under this Agreement and (ii) such information presented in a summary fashion as is necessary to report the accountants' conclusions to the auditing Party, and all such information shall be deemed Confidential Information of the Recording Party. Following completion of an audit, the independent public accounting firm shall, prior to distribution to the auditing Party, share its report with the audited Party. If the audited Party provides the independent public accounting firm with justifying remarks for inclusion in the report, the independent public accounting firm shall incorporate such remarks into its report prior to sharing the conclusions of such independent public accounting firm with the auditing Party. All costs and expenses incurred in connection with performing any such audit shall be paid by the auditing Party unless the audit discloses at least a [\*\*\*] shortfall with respect to Net Sales or excess with respect to costs or expenses, as applicable, in which case the Recording Party will bear the full cost of the audit for such calendar year. The auditing Party will be entitled to recover any shortfall in payments due to it (or overpayment made by it, as applicable) as determined by such audit, plus interest thereon calculated in accordance with Section 6.14. The documents from which were calculated the sums due under this Article 6 shall be retained by each Recording Party during the Term.

**6.14 Interest on Late Payments.** If either Party shall fail to make timely payment of any undisputed amount pursuant to this Article 6, any such payment that is not paid on or before the due date that is due under this Agreement shall bear interest, to the extent permitted by Laws, at the Applicable Rate, 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 JSC agrees.

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## 6.15 Tax Matters.

(a) Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by Laws (including, for the avoidance of doubt, withholding pursuant to section 1446 of the Tax Code, if applicable) in effect at the time of payment.

(b) Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the “Payor”) on behalf of the Party receiving the payment (the “Payee”) to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax. Any such Tax, to the extent withheld and paid to the appropriate Governmental Authority, shall be treated for all purposes of this Agreement as having been paid to the Payee. Any such Tax required to be withheld will be an expense of and borne by Payee.

(c) The Parties will cooperate with respect to all documentation required by any Governmental Authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. If the withholding tax rate is reduced according to the provisions of an applicable double tax treaty or regulations applicable thereto, no deduction or withholding shall be made (or a reduced amount shall be deducted or withheld), in each case as applicable, only if the Payor is timely furnished with necessary documents or certification by the Payee issued by the Governmental Authority certifying that the payment is exempt from Tax or subject to a reduced tax rate or the Payee otherwise satisfies the requirements to obtain the treaty benefit in question.

(d) If Payor had a duty to withhold Taxes in connection with any payment it made to Payee under this Agreement but Payor failed to withhold, and such Taxes were assessed against and paid by Payor, then Payee will indemnify and hold harmless Payor from and against such Taxes, except interest and penalties to the extent such failure is attributable to Payor’s gross negligence or willful misconduct. If Payor makes a claim under this Section 6.15(d), it will comply with the obligations imposed by Section 6.15(b) as if Payor had withheld Taxes from a payment to Payee.

## 6.16 Tax Returns.

(a) The Parties hereby agree to treat the activities giving rise to the Profits (Losses) in the United States as a partnership (the “Partnership”) for U.S. federal and state income Tax purposes upon receipt of Marketing Approval for any Product by or on behalf of Janssen or its Affiliate in the U.S. for a first Indication. Janssen shall act as the Tax Representative for the Partnership. The designation of Tax Representative for such partnership will be effective only for activities conducted by the parties pursuant to this Section 6.16(a). In performing its responsibilities, the Tax Representative shall consider the interests and requests of both Parties, and except as noted below, the Tax Representative will not make any Tax elections or take any other material actions affecting Tax matters of the Partnership without obtaining the prior written consent of Theravance, with any disagreements over Tax matters resolved by the JSC.

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(b) To the extent attributable to any activities outside the U.S., the Parties hereby agree to treat the activities giving rise to royalties on Net Sales of the Product outside the United States as required under the applicable Laws of the relevant jurisdiction (the “Ex-U.S. Territory Activities”). For the avoidance of doubt, the Ex-U.S. Territory Activities shall be separate and distinct from the Partnership. The Parties will keep separate books and records with respect to the Partnership and the Ex-U.S. Territory Activities, as applicable.

(c) The Parties hereby agree that 100% of any deductions for Tax purposes attributable to amounts paid or incurred by Theravance pursuant to this Agreement shall be deductible or amortizable solely by Theravance, and 100% of any deductions for Tax purposes attributable to amounts paid or incurred by Janssen pursuant to this Agreement shall be deductible or amortizable solely by Janssen. All Tax returns reflecting any such amounts shall be filed (and any available elections to effect such intent, including a remedial allocation election, shall be made) consistent with the foregoing.

(d) For every other purpose besides the preparation and reporting of U.S. partnership income tax returns, the Parties understand and agree that their legal relationship to each other under applicable Law with respect to all activities is as set forth in Section 13.12.

## ARTICLE 7

### INTELLECTUAL PROPERTY MATTERS

#### 7.1 Ownership of Inventions.

(a) **Sole Inventions.** Each Party shall solely own any Inventions made solely by it or its Affiliates’ employees, agents, or independent contractors during the Term (“Sole Inventions”).

(b) **Joint Inventions.** The Parties shall jointly own any Invention that is made jointly by employees, agents, or independent contractors of one Party or its Affiliates together with employees, agents, or independent contractors of the other Party or its Affiliates during the Term (“Joint Inventions”). All Patent Rights claiming Joint Inventions shall be referred to herein as “Joint Patent Rights.” Except to the extent a Party is expressly limited by the terms of this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Joint Patent Rights without the duty of accounting or seeking consent from the other Party; upon the reasonable request of either Party, the other Party shall execute documents that evidence or confirm the requesting Party’s right to engage in such activities. Inventorship shall be determined in accordance with U.S. patent laws.

7.2 **Disclosure of Inventions.** Each Party shall promptly disclose to the other Party, all Inventions made by such Party to which the other Party has rights hereunder, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from the other Party for additional information relating to such Inventions.

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### 7.3 Patent Prosecution.

(a) **Janssen Sole Patent Rights.** As between the Parties, Janssen shall have the sole and exclusive right to file, prosecute and maintain all Patent Rights claiming Janssen's Sole Inventions (collectively, the "Janssen Sole Patent Rights"), at its own cost and expense. Janssen shall consult with Theravance and keep Theravance reasonably informed of the status of the Janssen Sole Patent Rights and shall promptly provide Theravance with all material correspondence received from any patent authority in connection therewith. In addition, Janssen shall promptly provide Theravance with drafts of all proposed material filings and correspondence to any patent authority with respect to the Janssen Sole Patent Rights for Theravance's review and comment prior to the submission of such proposed filings and correspondence, *provided, however*, that all final decisions regarding such filings and correspondences shall rest solely in the discretion of Janssen. Janssen shall confer with Theravance and shall consider in good faith Theravance's comments with respect to the Janssen Sole Patent Rights, in each case prior to submitting such filings and correspondence. For the purpose of this Article 7, "prosecution" shall include conducting any *inter partes* review, post-grant review, or any other post-grant proceeding including any patent interference proceeding, opposition proceeding and reexamination.

(b) **Theravance Sole Patent Rights.**

(i) **Prior to the Opt-In Date.** Prior to the Opt-In Date, as between the Parties, Theravance shall have the sole right to file, prosecute and maintain all Theravance Patent Rights, including those claiming Theravance's Sole Inventions (the "Theravance Sole Patent Rights"), at its own cost and expense. Theravance shall consult with Janssen and keep Janssen reasonably informed of the status of the Theravance Patent Rights and shall promptly provide Janssen with all material correspondence received from any patent authority in connection therewith. In addition, Theravance shall promptly provide Janssen with drafts of all proposed material filings and correspondence to any patent authority with respect to the Theravance Patent Rights for Janssen's review and comment prior to the submission of such proposed filings and correspondence, *provided, however*, that all final decisions regarding such filings and correspondences shall rest solely in the discretion of Theravance. Theravance shall confer with Janssen and shall consider in good faith Janssen's comments with respect to the Theravance Patent Rights, in each case prior to submitting such filings and correspondence.

(ii) **After the Opt-In Date.** After the Opt-In Date, as between the Parties, Janssen shall have the first right to file, prosecute and maintain all Theravance Patent Rights, including the Theravance Sole Patent Rights, at its own cost and expense but in Theravance's name. Janssen shall consult with Theravance and keep Theravance reasonably informed of the status of the Theravance Patent Rights and shall promptly provide Theravance with all material correspondence received from any patent authority in connection therewith. In addition, Janssen shall promptly provide Theravance with drafts of all proposed material filings and correspondence to any patent authority with respect to the Theravance Patent Rights for Theravance's review and comment prior to the submission of such proposed filings and correspondence, *provided, however*, that all final decisions

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regarding such filings and correspondences shall rest solely in the discretion of Janssen. For clarity, Janssen's rights to file, prosecute and maintain Patent Rights pursuant to this Section 7.3 shall apply solely with respect to Theravance Patent Rights that Cover or are related to Compounds and Products that are subject to the Commercial License.

**(iii) Option to Prosecute and Maintain Patent Rights.** If Janssen decides not to file or, after filing to no longer prosecute or maintain, any Theravance Patent Rights in any jurisdiction in the Territory, it shall notify Theravance in writing at least sixty (60) days prior to any filing or payment due date or any other due date that requires action to prevent such loss of rights. Thereafter, Theravance shall have the sole right to file, prosecute, maintain, enforce and defend such Theravance Patent Rights in such jurisdiction at its own cost and expense, the Commercial License with respect to such Theravance Patent Right shall be non-exclusive, and Janssen's rights with respect to the prosecution and enforcement of such Theravance Patent Right under this Section 7.3 and Section 7.4 shall terminate; *provided, however*, that prior to commencing any suit or action with respect to any such Theravance Patent Right, Theravance shall first notify Janssen of its intention to commence such suit or action, and shall not commence such suit or action if, within thirty (30) days of such notice, Janssen identifies to Theravance in good faith and reasonable detail a material risk of a material negative impact on the Theravance Patent Rights resulting directly from such a suit or action, taking into account the potential impact on the value of the Product worldwide.

**(c) Joint Patent Rights.** As between the Parties, Janssen shall have the first right to file, prosecute and maintain all Joint Patent Rights, at its own cost and expense. Janssen shall consult with Theravance and keep Theravance reasonably informed of the status of the Joint Patent Rights and shall promptly provide Theravance with all material correspondence received from any patent authority in connection therewith. In addition, Janssen shall promptly provide Theravance with drafts of all proposed material filings and correspondence to any patent authority with respect to the Joint Patent Rights for Theravance's review and comment prior to the submission of such proposed filings and correspondences. Janssen shall confer with Theravance and consider in good faith Theravance's comments prior to submitting such filings and correspondences, *provided, however*, that all final decisions regarding such filings and correspondences shall rest solely in the discretion of Janssen. If Janssen decides to no longer prosecute or maintain any Joint Patent Right in any jurisdiction, it shall notify Theravance in writing at least sixty (60) days prior to any filing or payment due date or any other due date that requires action to prevent such loss of rights. Thereafter, Theravance shall have the right to prosecute and maintain such Joint Patent Right in such jurisdiction.

**(d) Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided in this Section 7.3, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

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## 7.4 Patent Enforcement.

**(a) Notification.** If either Party becomes aware of (i) any existing or threatened infringement, misappropriation or other violation or misuse by a Third Party of any Theravance IP or Joint Patent Rights, (ii) a declaratory judgment action asserting the invalidity, unenforceability or non-infringement of any Theravance IP or Joint Patent Rights, or (iii) an MAA for a Generic Product referencing a Product submitted to a Party or a Regulatory Authority, it shall promptly notify the other Party in writing to that effect, and the Parties will consult with each other regarding any actions to be taken.

### **(b) Enforcement Rights.**

**(i)** Prior to the Opt-In Date, Theravance has the sole right to enforce and defend the Theravance Patent Rights. After the Opt-In Date, Janssen shall have the first right, but not the obligation, in the case of the Theravance Patent Rights to bring an appropriate suit or other action against any person or entity allegedly infringing any Theravance Patent Rights and to defend against any declaratory judgment action against any Theravance Patent Rights. Theravance shall provide reasonable assistance to Janssen in such enforcement or defense, at Janssen's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by Janssen. Janssen shall consult with Theravance and keep Theravance reasonably informed of the status of the enforcement of such Theravance Patent Rights, as the case may be. Janssen shall consider Theravance's comments with respect to the enforcement of such Theravance Patent Rights in good faith. Prior to settling any such suit or action, Janssen shall notify Theravance in writing as to the material terms of such proposed settlement and shall not execute such settlement without Theravance's written consent if Theravance identifies to Janssen in reasonable detail a material risk of a material negative impact on the Theravance Patent Rights, taking into account the potential impact on the value of the Product worldwide as a result of such settlement. If Janssen recovers monetary damages in such claim, suit or action, such recovery shall be allocated in accordance with this Section 7.4. With respect to litigation in the U.S., all costs and recoveries of the Parties in such litigation will be included in the Profit (Loss) calculation in accordance with Section 6.6. [\*\*\*]. For clarity, Janssen's enforcement rights under this Section 7.4 shall apply solely with respect to Theravance Patent Rights that Cover or are related to Compounds and Products that are subject to the Commercial License.

**(ii)** If Janssen does not, within ninety (90) days after its receipt or delivery of notice under Section 7.4(a) or ten (10) days before the expiration date for filing an appropriate suit or responding to or taking any action (as applicable), initiate and prosecute any legal action to enforce or defend the Theravance Patent Rights with respect an infringement or declaratory judgment, then Theravance shall have the right, but not the obligation, to commence such a suit or take such an action to enforce the applicable Theravance Patent Rights. In such event, Janssen shall take appropriate actions in order to enable Theravance to commence a suit or take the actions set forth in the preceding sentence. Prior to settling any such suit or action, Theravance shall notify Janssen in writing as to the material terms of such proposed settlement and shall not execute such settlement without Janssen's written consent if Janssen identifies to Theravance in reasonable detail a

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material risk of a material negative impact on the Theravance Patent Rights, taking into account the potential impact on the value of the Product worldwide as a result of such settlement. Prior to Theravance commencing such a suit or action, Theravance shall consider in good faith any reasonable business concerns, of which Janssen notifies Theravance in writing within ninety (90) days after Janssen's receipt or delivery of notice under Section 7.4(a). If Janssen identifies to Theravance in reasonable detail a material risk of a material negative impact on the Theravance Patent Rights resulting directly from such a suit or action, taking into account the potential impact on the value of the Product worldwide, then Theravance shall not commence any such suit or action. If Theravance recovers monetary damages in such claim, suit or action, such recovery shall be allocated in accordance with this Section 7.4. With respect to litigation in the U.S., all recoveries of the Parties in such litigation (after Theravance has recovered its costs and expenses (including those reimbursed to Janssen) incurred in conducting such litigation) will be included in the Profit (Loss) calculation in accordance with Section 6.6. [\*\*\*].

**(c) Collaboration.** Each Party shall provide to the enforcing Party reasonable assistance in such enforcement under this Section 7.4, at such enforcing Party's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by the enforcing Party. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any such efforts. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

## **7.5 Enforcement of Janssen Sole Patent Rights and Joint Patent Rights.**

**(a)** Janssen shall have the sole right, but not the obligation, in the case of the Janssen Sole Patent Rights and first right, but not the obligation, in the case of the Joint Patent Rights to bring an appropriate suit or other action against any person or entity allegedly infringing any Janssen Sole Patent Rights or Joint Patent Rights, as the case may be, and to defend against any declaratory judgment action against any Janssen Sole Patent Rights or Joint Patent Rights, as the case may be. Theravance shall provide reasonable assistance to Janssen in such enforcement or defense, at Janssen's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by Janssen. Prior to settling any such suit or action with respect to Joint Patent Rights, Janssen shall notify Theravance in writing as to the material terms of such proposed settlement and shall not execute such settlement without Theravance's written consent if Theravance identifies to Janssen in reasonable detail a material risk of a material negative impact on the Joint Patent Rights, taking into account the potential impact on the value of the Product worldwide as a result of such settlement. Except as set forth below in this Section 7.5(a), if Janssen recovers monetary damages in such claim, suit or action with respect to the Janssen Sole Patent Rights, such recovery shall be retained by Janssen. If Janssen recovers monetary damages in such claim, suit or action with respect to the Joint Patent Rights, any portion of such recovery remaining after Janssen recoups its

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costs and expenses associated with such litigation shall be shared equally by the Parties. Notwithstanding the foregoing, to the extent that Janssen enforces a Janssen Sole Patent Right or Joint Patent Right against a Product sold by a Third Party or a product sold by a Third Party that directly competes with a Product sold by Janssen, or its Affiliates or sublicensees, in each case, in the U.S., all costs and recoveries of the Parties in such litigation will be included in the Profit (Loss) calculation in accordance with Section 6.6; provided that Janssen shall promptly inform Theravance of its intent to bring such an enforcement action, and shall keep Theravance fully informed with respect to the progress of such enforcement action and consider in good faith any comments provided by Theravance with respect thereto.

(b) In the case of any existing or threatened infringement of, or declaratory judgment against, any Joint Patent Rights, if Janssen does not, within ninety (90) days after written request by Theravance or ten (10) days before the expiration date for filing an appropriate suit or responding to or taking any action (as applicable), commence a suit to enforce the applicable Joint Patent Right or take other action to defend such declaratory judgment action with respect to the applicable Joint Patent Right, and does not identify to Theravance in reasonable detail a material risk of a material negative impact on the Joint Patent Rights resulting directly from such a suit or action, taking into account the potential impact on the value of the Product worldwide, then Theravance shall have the right, but not the obligation, to commence such suit or take such action. Janssen shall provide reasonable assistance to Janssen in such enforcement or defense, at Theravance's request and expense, including joining such action as a party plaintiff to ensure legal standing if required by applicable Laws to pursue such action or if requested by Theravance. Theravance shall not settle any such suit or action in any manner that would have a material adverse impact on the applicable Joint Patent Rights or the ability to sell Products, if Janssen identifies to Theravance in reasonable detail a material risk of a material negative impact on the Joint Patent Rights as a result of such settlement. If Theravance recovers monetary damages in such claim, suit or action with respect to the Joint Patent Rights, any portion of such recovery remaining after Theravance recoups its costs and expenses associated with such litigation, shall be shared equally by the Parties. Notwithstanding the foregoing, to the extent that Theravance enforces a Joint Patent Right against a Product sold by a Third Party or a product sold by a Third Party that directly competes with a Product sold by Janssen, or its Affiliates or sublicensees, in each case, in the U.S., all costs and recoveries of the Parties in such litigation will be included in the Profit (Loss) calculation in accordance with Section 6.6; provided that Theravance shall promptly inform Janssen of its intent to bring such an enforcement action, and shall keep Janssen fully informed with respect to the progress of such enforcement action and consider in good faith any comments provided by Janssen with respect thereto.

**7.6 Patent Term Extensions.** The Parties shall cooperate in seeking and obtaining patent term extensions (including any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to the Theravance Patent Rights or the Joint Patent Rights and Products. Janssen shall have the sole right and responsibility to obtain patent term extensions or supplemental protection certificates or their equivalents with respect to the Janssen Sole Patent Rights and the Product, and shall report to Theravance on the status thereof.

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**7.7 Personnel Obligations.** Prior to beginning work under this Agreement relating to any Development of a Product, each employee, agent or independent contractor of a Party or its Affiliates shall be bound by invention assignment obligations that are consistent with the obligations of such Party in this Article 7, including: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to such Party all of the right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any Patent Rights; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) complying with obligations of confidentiality and non-use consistent with those contained in this Agreement.

**7.8 Trademarks.** Subject to Section 5.6, Janssen shall have the sole and exclusive right to, in its sole discretion, select (and conduct clearance searches for) the trademarks used to brand the Products in the Territory for the Products, which may vary by country or within a country (the "Product Marks"). As between the Parties, Janssen shall own all rights in the Product Marks and shall register and maintain, in its sole discretion and at its own cost and expense, the Product Marks in the countries and regions in the Territory that it determines to be appropriate. Janssen shall have the sole right, in its discretion and at its expense, to defend and enforce the Product Marks.

## ARTICLE 8

### REPRESENTATIONS AND WARRANTIES; COVENANTS

**8.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

(a) **Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated or otherwise formed.

(b) **Corporate Power, Authority and Binding Agreement.** As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) **No Conflicts.** It has not entered, and shall not enter, into any material agreement that is in conflict with the rights granted by it under this Agreement, and has not taken and shall not take any action that would in any material way prevent it from granting the rights granted to, or contemplated to be granted to, the other Party under this Agreement, or that would

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otherwise materially conflict with or adversely affect such other Party's rights under this Agreement.

**(d) Anti-Corruption Laws.**

**(i)** Each Party understands that the other Party is required to and does abide by the United States Foreign Corrupt Practices Act ("FCPA"), the United Kingdom Bribery Act ("UKBA") and any other applicable anti-corruption laws (collectively, the "Anti-Corruption Laws"). Each Party represents and warrants that no one acting on its behalf with respect to its rights and obligations arising from this Agreement will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or other thing of value to anyone as an inducement or reward for favorable action or forbearance from action or the exercise of influence (a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other person or entity in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

**(ii)** Without limiting any other provision in this Section 8.1(d), either Party may suspend payment to the other hereunder, upon prior written notice, if (i) the other Party becomes subject to an investigation of potential violations of the FCPA or (ii) the other Party, in the reasonable determination of the paying party, fails to comply with the provisions of any Anti-Corruption Laws, including the FCPA, and such investigation, or such failure, would reasonably be expected to adversely impact in any significant manner the Commercialization of the Product in the Field in the Territory.

**(iii)** Each Party warrants that all persons acting on its behalf with respect to its rights and obligations arising from this Agreement will comply with all applicable Laws in connection with all work conducted hereunder, including the Anti-Corruption Laws if any, prevailing in the country(ies) in which it has its principal places of business or performs work hereunder.

**(iv)** Each Party further warrants and represents that should it learn or have reason to suspect any breach of its covenants in this Section 8.1(d), it will immediately notify the other Party.

**(v)** Each Party may appoint a certified public accounting firm to perform a financial audit to determine whether the other Party is in compliance with the terms of this Section 8.1(d). Each Party hereby agrees to grant the certified public accounting firm commercially reasonable access to its books, records, systems and accounts to the extent they pertain to transactions covered by this Agreement and are necessary for such purpose.

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**(e) Trade Control Laws.**

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

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

**(iii)** No Compound or Product will be directly or indirectly shipped by the other Party to any country subject to U.S. or U.N. economic sanctions without the necessary licenses, even for transfer to non-sanctioned countries.

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

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

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

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

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**8.2 Additional Representations and Warranties of Theravance.** Theravance represents and warrants and, as applicable, covenants to Janssen as follows, as of the Effective Date:

(a) **Title; Encumbrances.** Theravance is the sole and exclusive owner of the Patent Rights listed on Exhibit A as owned by Theravance, and the exclusive licensee of the Patent Rights listed on Exhibit A as licensed by Theravance, and has the full and legal rights and authority to license to Janssen the Theravance IP for the purposes expressly provided in this Agreement.

(b) **License Agreements.** Exhibit A identifies any license agreement pursuant to which any Theravance Patent Rights that Cover a Compound are licensed to Theravance or any of its Affiliates. Each such license agreement is in effect and is valid and binding on Theravance or such Affiliate, enforceable in accordance with its terms, and neither Theravance nor any of its Affiliates, nor to the knowledge of Theravance is any third party, in material breach or default under any such agreement.

(c) **Patent Matters.** Exhibit A is an accurate listing of all patents and patent applications Controlled by Theravance as of the Effective Date that include any claim Covering or that may be necessary or useful for the development, manufacture, use, offer for sale, sale or import of the Compounds or the Initial Products as contemplated herein.

(d) **Royalties and Payments.** Theravance is not subject to any royalty or other payment obligation to any Third Party with respect to the practice, or grant of rights to Janssen to practice, any of the Theravance Patent Rights or Theravance Know-How, in each case existing as of the Effective Date, other than as set forth in Exhibit A.

(e) **Validity.** To Theravance's knowledge, there is no fact or circumstance that would cause Theravance to reasonably conclude that any of the issued patents in the Theravance Patent Rights is invalid or unenforceable.

(f) **Inventorship.** To Theravance's knowledge, the inventorship of each of the Theravance Patent Rights is properly identified on the corresponding patent or patent application, and Theravance or its Affiliate is listed in the records of the appropriate governmental authorities as the sole and exclusive owner of record, if applicable, for each registration, grant and application included in such Theravance Patent Rights that are owned by Theravance or such Affiliate.

(g) **Good Standing.** All official fees, maintenance fees and annuities for the Theravance Patent Rights have been paid and all administrative procedures with Governmental Authorities are in process or have been completed for the Theravance Patent Rights such that the Theravance Patent Rights are pending, subsisting or in good standing (as applicable).

(h) **Notice of Infringement.** Theravance has not received any written notice or written threat from any Third Party asserting or alleging that any Development or use of any Compounds or Products by Theravance infringed or that Commercialization of the Compounds or Products would infringe the issued or pending Patent Rights of such Third Party and, to the

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knowledge of Theravance, the commercial making, using, selling, offering for sale or importing of the Initial Compound would not infringe the Patent Rights of any Third Party.

**(i) Notice of Misappropriation.** Theravance has not received any written notice or written threat from any Third Party asserting or alleging that any Development of use of Compounds or Products by Theravance prior to the Effective Date misappropriated or violated the intellectual property rights of such Third Party.

**(j) Third Party Infringement.** To Theravance's knowledge, [\*\*\*] no Third Party is infringing or has infringed any issued Theravance Patent Rights, misappropriated any Theravance Know-How or violated any other Theravance intellectual property rights, and Theravance is not aware of any Compound or Product of any Third Party that, if commercially sold, would infringe the Theravance Patent Rights.

**(k) No Proceeding.** There are no pending, and to Theravance's knowledge, no threatened, adverse actions, suits or proceedings (including interferences, reissues, reexaminations, cancellations, oppositions, nullity actions, invalidation actions or post-grant reviews) against Theravance or its Affiliates involving the Theravance IP or Products.

**(l) Compliance.** Theravance's Development of the Compounds and the Products prior to the Effective Date has been conducted in compliance with all Applicable Laws and regulatory standards in all material respects.

**(m) No Debarment.** As of the Effective Date, neither Theravance nor any of its Affiliates, employees, consultants or contractors is or has been debarred by any Regulatory Authority.

### **8.3 Mutual Covenants.**

**(a) No Debarment.** In the course of the Development and manufacture of the Products, neither Party shall use any employee or consultant who has been debarred by any Regulatory Authority or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party in writing promptly upon becoming aware that any of its employees or consultants involved in the Development or manufacture of the Compound or the Products has been debarred or is the subject of debarment proceedings by any Regulatory Authority. Upon written request from the other Party, a Party shall, within ten (10) days provide written confirmation that it has complied with the foregoing obligation.

**(b) Compliance.** Each Party and its Affiliates shall comply in all material respects with all Laws applicable to the Development, manufacture and Commercialization of Products and performance of its obligations under this Agreement, including, to the extent applicable, the statutes, regulations and written directives of the FDA (including GCP, GLP, and GMP), the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law,

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42 U.S.C. § 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

**8.4 Disclaimer.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO ANY PRODUCT WILL BE ACHIEVED.

## ARTICLE 9 INDEMNIFICATION

**9.1 Indemnification by Theravance.** [\*\*\*].

**9.2 Indemnification by Janssen.** [\*\*\*].

**9.3 Losses from Third Party Claims; Exclusion of Costs Due to Breach or Subject to Indemnification.** In the event of any Claims that result in Losses being incurred by any Theravance Indemnitee or any Janssen Indemnitee, where such Claims and associated Losses: (a) are not within the indemnification obligations described in Section 9.1 or 9.2; and (b) arise as a result of the Development, Manufacture or Commercialization activities conducted by either Party on or after the Effective Date with respect to any Product sold, or to be sold, in the United States, such Losses shall constitute Allowable Expenses to be included in the Profit (Loss) calculation pursuant to Section 6.6. If any such Claim arises, the Party against which such Claim is brought shall promptly notify the other Party in writing of the Claim, and the JSC shall determine which Party shall manage and control the defense of such Claim and its settlement (the “Defending Party”). In the event that the JSC fails to agree with respect to which Party shall be the Defending Party, the Party against which such Claim is brought shall be the Defending Party and shall manage and control, at its sole expense, the defense of the Claim and its settlement. Notwithstanding the foregoing, no settlements shall be finalized without obtaining approval of the JSC, taking the other Party’s (the “Non-Defending Party”) comments into consideration in good faith. The Non-Defending Party shall cooperate with Defending Party and may, at its discretion and expense, be represented in any such action or proceeding.

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**9.4 Indemnification Procedures.** The Party claiming indemnity under this Article 9 (the “Indemnified Party”) shall give written notice to the Party from whom indemnity is being sought (the “Indemnifying Party”) promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however*, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. Unless the settlement involves only the payment of money, the Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, such consent not to be unreasonably withheld, conditioned or delayed. So long as the Indemnifying Party is conducting the defense of the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 9.

**9.5 Insurance.** Each Party, at its own expense, shall procure and maintain product liability insurance, self-insurance or captive insurance adequate to cover the activities to be conducted by such Party and its obligations under this Agreement that are consistent with normal business practices of prudent companies similarly situated; *provided* however, that in no event shall such product liability insurance be written in amounts less than [\*\*\*] per claim or per occurrence and annual aggregate. All such insurance shall include worldwide coverage. Prior to the initiation of any Clinical Trial of a Compound or Product, the Party responsible for such Clinical Trial shall secure, and maintain in full force and effect, clinical trial insurance as required by applicable Law in those territories where such Clinical Trial shall be conducted. It is understood that such insurance shall not be construed to create a limit of either Party’s liability with respect to its indemnification obligations under this Article 9. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change of such insurance that could materially adversely affect the rights of such other Party hereunder. Notwithstanding the foregoing, either Party’s failure to maintain adequate insurance shall not relieve that Party of its obligations set forth in this Agreement. The Parties acknowledge and agree that Janssen may meet its obligations under this Section 9.5 through self-insurance consistent with the levels set forth herein with prior written notice to Theravance. In such event, Janssen shall provide a written certification of such self-insurance to Theravance upon request.

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**ARTICLE 10**  
**CONFIDENTIALITY**

**10.1 Confidentiality.** Each Party agrees that, during the Term and for a period of ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other 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;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

As between the Parties, each Party shall own its Confidential Information.

**10.2 Authorized Disclosure.** Notwithstanding the obligations set forth in Section 10.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; *provided* that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(b) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquirer, merger partner, licensee, sublicensee, or other financial or commercial partner

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for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; *provided* that in connection with such disclosure, such Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and, in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement; or

(c) such disclosure is reasonably necessary to comply with applicable Laws, rules or regulations promulgated by Governmental Authorities or applicable securities exchanges, court order, or administrative subpoena or order; *provided* that the Party subject to such Laws, rules, regulations, court order, or administrative subpoena or order shall (i) promptly notify the other Party prior to making such required disclosure; (ii) provide reasonable prior advance notice of the proposed text of such disclosure to the other Party for its prior review; (iii) use good faith efforts to incorporate the reviewing Party's reasonable comments thereon and (iv) use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

### **10.3 Technical Publication.**

(a) During the Term, Theravance shall have the right to publish and otherwise publicly disclose peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out by or on behalf of the Parties under the Collaboration Plans, including on [clinicaltrials.gov](http://clinicaltrials.gov), subject to compliance with this Section 10.3. In the event that Theravance desires to make such a publication or public presentation of any Collaboration Know-How, it shall provide Janssen with at least thirty (30) days to review and comment on such proposed publication or presentation prior to its submission for publication or presentation. Janssen shall have the right to delay publication or presentation for up to an additional sixty (60) days in order to enable patent applications protecting each Party's rights in such information to be filed, and Janssen shall also have the right to prohibit the disclosure of any of its Confidential Information contained in any such proposed publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined, in accordance with customary standards.

(b) Prior to the Opt-In Date, Janssen shall not make any publications or presentations regarding the results of the Collaboration Plans or the Products without Theravance's prior written consent. After the Opt-In Date, Janssen shall have the right to publish and otherwise publicly disclose peer reviewed manuscripts, or provide other forms of public disclosure including abstracts and presentations, of results of studies carried out by or on behalf of the Parties under the Collaboration Plans for the applicable Product concerning the Development and Commercialization of such Product, including on [clinicaltrials.gov](http://clinicaltrials.gov), subject to compliance with this Section 10.3. In the event that Janssen desires to make such a publication or public presentation of any Collaboration Know-How, it shall provide Theravance with at least thirty (30) days to review and comment on such proposed publication or presentation prior to its submission for publication or presentation. Theravance shall have the right to delay publication or presentation for up to an additional sixty (60) days in order to enable patent applications protecting each Party's rights in such information to be filed, and Theravance shall also have the right to prohibit the

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disclosure of any of its Confidential Information contained in any such proposed publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined, in accordance with customary standards.

#### **10.4 Publicity; Term of Agreement.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 10.4 or Section 10.2.

(b) Each Party may, but is not obligated to, make a public announcement of the execution of this Agreement in accordance with this Section 10.4(b), which shall be issued at a time to be mutually agreed by the Parties no later than two (2) Business Days after the execution of this Agreement. Except as required to comply with applicable Laws or as permitted by Section 10.2, each Party agrees not to issue any press release or other public statement disclosing any information relating to this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. A Party commenting on such a proposed public announcement shall provide its comments, if any, within three (3) Business Days after receiving the text of the public announcement for review. Neither Party shall be required to seek the permission of the other Party to repeat any information that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 10.4(b), provided such information remains accurate as of such time.

(c) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. In the event that a Party determines in good faith that such a filing is required, such Party shall request confidential treatment of all confidential information herein, including the sensitive commercial, financial and technical terms hereof, to the extent such confidential treatment may be reasonably available to such Party. In the event of any such filing, the filing Party shall provide the other Party with a copy of this Agreement marked to show provisions for which such filing Party intends to seek confidential treatment within a reasonable amount of time (not to exceed five (5) days) prior to filing and shall use good faith efforts to incorporate the other Party's reasonable comments thereon to the extent consistent with applicable Laws or rules or regulations promulgated by Governmental Authorities or applicable securities exchanges. Each Party shall be responsible for its own legal and other external costs in connection with any such filing.

### **ARTICLE 11**

#### **TERM AND TERMINATION**

**11.1 Term.** Unless earlier terminated in accordance with this Article 11, the term of this Agreement (the "Term") shall commence on the Effective Date and [\*\*\*].

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**11.2 Termination by Janssen Without Cause.** Janssen may terminate this Agreement without cause or reason upon [\*\*\*] written notice to Theravance.

**11.3 Termination by Janssen for Cause.** Janssen may terminate this Agreement, at any time after the Effective Date, at any time upon [\*\*\*] written notice to Theravance, [\*\*\*].

**11.4 Termination by Either Party for Breach.** A Party (the “Terminating Party”) shall have the right to terminate this Agreement upon written notice to the other Party (the “Breaching Party”) in the event the Breaching Party materially breaches this Agreement and, after receiving written notice from the Terminating Party identifying such material breach in reasonable detail, fails to cure such material breach within [\*\*\*] from the date of such notice (the “Cure Period”). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 11.4 shall become effective at the end of the Cure Period unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period (or, if such breach (other than a breach of payment obligations) is not reasonably able to be cured within the Cure Period, such termination shall not become effective until the earlier of the date such breach is cured or [\*\*\*] after notice of termination is given pursuant to this Section 11.4, whichever is earlier, *provided that* (i) the Breaching Party notifies the Terminating Party of its plan for curing such breach during the Cure Period, (ii) the Breaching Party commences such plan during the Cure Period and (iii) the Breaching Party uses Commercially Reasonable Efforts to perform such plan and cure such breach as soon as reasonably practicable). The right of either Party to terminate this Agreement as provided in this Section 11.4 shall not be affected in any way by such Party’s waiver or failure to take action with respect to any previous breach under this Agreement.

**11.5 Termination for Insolvency.** Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within sixty (60) days of its filing, or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

**11.6 Additional Effects of Expiration or Termination.**

**(a) Termination Prior to the Opt-In Date.** In the event Janssen terminates pursuant to Section 11.2 prior to the Opt-In Date, neither Party shall have any further obligation to the other, except for the obligations

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of both Parties set forth in Section 11.6(f) and Section 11.6(i).

**(b) Ongoing Development Activities.** Except as set forth below, Janssen shall have no further obligation to conduct Development activities with respect to a Compound or Product after the date of notice of termination. After the Opt-In Date, if Janssen is conducting any Development activity with respect to a Compound or Product on the date of notice of termination, then Theravance shall notify Janssen within [\*\*\*] after the notice of termination: (i) with regard to any Clinical Trial, whether Theravance elects to have Janssen (A) complete such Clinical Trial on behalf of Theravance (unless Janssen reasonably believes there is a Material Safety Issue that should prevent the continuation of such Clinical Trial), (B) wind down such Clinical Trial as soon as practicable, subject to compliance with ethical and legal requirements or (C) transfer such Clinical Trial to Theravance as soon as practicable; and (ii) with regard to any other Development activity, whether Theravance elects to have Janssen wind down or transfer such activity to Theravance. Notwithstanding the foregoing, if Janssen terminates this Agreement pursuant to Section 11.3, 11.4 or 11.5, then this Section 11.6(b) shall not apply and Janssen shall wind down any ongoing Development activities as soon as practicable after the date of notice of termination, subject to compliance with ethical and legal requirements; and each Party shall bear its own expenses incurred pursuant to such wind down. After the Opt-In Date:

**(i)** If Theravance notifies Janssen of its election to have Janssen complete a Clinical Trial on behalf of Theravance, Janssen and Theravance will, as necessary, negotiate in good faith a separate agreement pursuant to which Janssen would complete such Clinical Trial. If the Parties fail to reach agreement within [\*\*\*] after Theravance makes such election, Janssen may wind down such Clinical Trial, subject to compliance with ethical and legal requirements or, if requested by Theravance, transfer such Clinical Trial to Theravance.

**(ii)** If Theravance notifies Janssen of its election to have Janssen wind down such Clinical Trial or other Development activity (or fails to provide notice within such [\*\*\*] period), then Janssen shall wind-down such Clinical Trial or Development activity as soon as practicable, subject to compliance with ethical and legal requirements.

**(iii)** If Theravance notifies Janssen of its election to have Janssen transfer such Clinical Trial or other Development activity to Theravance, then Janssen shall use Commercially Reasonable Efforts to transfer, and Theravance shall use Commercially Reasonable Efforts to assume, such Clinical Trial or other Development activity as promptly as practicable (and, in any event, [\*\*\*]) after the effective date of termination.

**(iv)** The costs of ongoing Clinical Trials or other Development activity contemplated by this Section 11.6(b) shall be borne as follows:

1. By Theravance after the effective date of termination, [\*\*\*].
2. By Theravance after the effective date of termination, [\*\*\*].

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3. In accordance with Section 6.3, with [\*\*\*].

a. Except with respect to the wind-down of a Clinical Trial in accordance with Section 11.6(b)(ii), for a total of [\*\*\*] after the notice of termination delivered pursuant to Section 11.2; or

b. With respect to the wind-down of a Clinical Trial in accordance with Section 11.6(b)(ii), [\*\*\*].

(v) If Janssen terminates this Agreement pursuant to Section 11.2 after commercial launch of the Initial Product, [\*\*\*].

(c) [\*\*\*].

(d) Upon termination of this Agreement, [\*\*\*].

(e) **Licenses.**

(i) The licenses and other rights granted to either Party under this Agreement, other than those that expressly survive termination of this Agreement (if any), shall terminate on the expiration or effective date of termination of this Agreement.

(ii) Janssen shall, and hereby does, grant to Theravance, effective as of the effective date of termination of this Agreement or expiration of this Agreement pursuant to Section 11.1(a), a non-exclusive, perpetual, royalty-free (except as set forth in Section 11.6(j)), freely sublicensable, transferable license under any Collaboration Know-How, Janssen's Sole Inventions, Janssen Sole Patent Rights, Joint Invention and Joint Patent Rights ("Termination IP") to Develop, make, have made, use, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit, Manufacture and Commercialize Compounds and Products in the Field in the Territory. The Termination IP shall not include any Patent Rights or Know-How Controlled by Janssen or its Affiliates prior to the Effective Date. Upon Theravance's request, with regard to any compound that is a Compound whose composition of matter is Covered by a Valid Claim of the Theravance Patent Rights, the Parties will negotiate in good faith the terms on which any Combination Product IP Controlled by Janssen or its Affiliates would be included in the Termination IP for use with such compound.

(f) **Regulatory Materials.** Janssen shall, and hereby does, assign to Theravance, as of the effective date of termination of this Agreement, all its right, title and interest in, to and under all of Janssen's and its Affiliates' and sublicensees' interest in any Regulatory Material solely related to the Compounds and Products, including any Marketing Approvals for the Compounds and Products, and Janssen shall transfer all such Regulatory Material ("Transferred Regulatory Materials") to Theravance promptly after such effective date of termination.

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**(g) Provision of Product.** Upon termination of this Agreement, at Theravance's request, Janssen shall assign and transfer to Theravance any inventory of Compounds or Products then in Janssen's or any of its Affiliate's possession or control subject to Theravance's reimbursement of Janssen's reasonable costs incurred in acquiring such inventory and with respect to shipping thereof.

**(h) Trademarks.** Upon termination of this Agreement pursuant to Section 11.2, 11.3, or by Theravance pursuant to Section 11.4 or 11.5, Janssen shall assign to Theravance all worldwide rights in and to any and all Product Marks used to commercialize the Product in the Territory, including all trademark applications and registrations. For clarity, Product Marks do not include the Janssen House Marks. Theravance shall be solely responsible for all costs and expenses related to the assignments, including recordal of the same. For a period of up to six (6) months after the termination date, at Theravance's cost and expense, (i) Janssen shall provide to Theravance the necessary information to permit Theravance to effect and perfect the transfer of the applications and registrations of the Product Marks and (ii) Janssen shall reasonably cooperate with Theravance in executing appropriate documents to effectuate the transfer or assignment for the Product Marks worldwide that are in the name of Janssen or any of its Affiliates. After such period, Janssen shall have no further obligation with respect to the matters covered by this Section 11.6(h). If there is a termination for any other reason other than pursuant to Section 11.2 or 11.3 or by Theravance pursuant to Section 11.4 or 11.5, the Parties shall negotiate in good faith any transfer of the Product Marks taking into account the circumstances surrounding such termination.

**(i) Confidential Information.**

**(i)** Janssen shall, within thirty (30) days after the effective date of expiration or termination of this Agreement, and at Janssen's expense, return or destroy, at Theravance's election, all Theravance Know-How and other Confidential Information of Theravance (provided that (1) Janssen may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (2) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties, Janssen's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6(i) and (3) Janssen may retain and continue to use Theravance Know-How and other Confidential Information of Theravance to practice any licenses and other rights granted to Janssen under this Agreement that expressly survive expiration of this Agreement).

**(ii)** Theravance shall, within thirty (30) days after the effective date of expiration or termination of this Agreement, and at Theravance's expense, return or destroy, at Janssen's election, all Confidential Information of Janssen (provided that (1) Theravance may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only, (2) it is acknowledged that, with regard to any such Confidential Information disclosed to subcontractors, consultants, agents, advisors and other Third Parties, Theravance's use of Commercially Reasonable Efforts to return or destroy such Confidential Information shall satisfy its obligation under this Section 11.6(i) and (3) Theravance may retain and continue to use Confidential

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Information of Janssen to practice any licenses and other rights granted to Theravance under this Agreement that expressly survive expiration or termination of this Agreement).

**(j) Post-Termination Royalties to Janssen.** [\*\*\*].

**(k) General Assistance.** Janssen shall take such other actions, and execute any instruments, assignments and documents, at Theravance's expense, as reasonably requested by Theravance as may be necessary to effect the foregoing provisions of this Section 11.6.

**(l) Additional Effects of Expiration or Termination for any Reason.** Termination or expiration of this Agreement will not relieve the Parties of any accrued or unpaid obligations occurring prior to such expiration or termination, including with respect to Deferrable Costs and interest accrued thereon, and any such expiration or termination will be without prejudice to the rights of either Party accruing prior to such expiration or termination. The Parties acknowledge and agree that termination of this Agreement is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as expressly agreed to otherwise herein. The provisions of the following Sections and Articles shall survive expiration or termination of this Agreement for any reason: Articles 1, 10, 12, and 13, and Sections 2.1(c), 2.3(c), 4.4(j), 4.5(b) (iv), 6.3 (solely with respect to amounts incurred prior to expiration or termination), 6.4-6.5 (with respect to any milestone achieved prior to expiration or termination), 6.6 (with respect to the period prior to expiration or termination), 6.8 (with respect to sales prior to expiration or termination), 6.9 (with respect to periods prior to expiration or termination), 6.10-6.12, 6.13 (for the period set forth therein), 6.14 - 6.15, 6.16 (with respect to Profits (Losses) during the Term), 7.1, 7.2, 8.4, 9.1-9.4, 9.5 (for three years), the last sentence of 11.1, and 11.6. Except as otherwise expressly provided in this Agreement, all rights and obligations of the Parties hereunder shall terminate upon expiration or termination of this Agreement.

**(m)** [\*\*\*]. In the event that Janssen suffers damages based on a material breach of this Agreement by Theravance ("Subject Damages"), and such breach is not cured within the Cure Period, the Parties shall attempt in good faith to resolve any dispute regarding the existence of such breach or the amount of the Subject Damages pursuant to the mechanisms set forth in Sections 12.2(a) and (b). If, after such attempts, the Parties are not in agreement as to the existence of a material breach of this Agreement or the amount of Subject Damages [\*\*\*] until the Parties resolve the disagreement pursuant to the mechanism set forth in Section 12.2(c); provided that Janssen may not, [\*\*\*]. After a decision regarding the Subject Damages is provided pursuant to the mechanism set forth in Section 12.2(c), Janssen shall (in accordance with the timeframe proscribed in the arbitrator's decision) [\*\*\*].

## ARTICLE 12 DISPUTE RESOLUTION

**12.1 Dispute Resolution.** The Parties recognize that a dispute may arise relating to this Agreement ("Dispute"). Any Dispute shall be resolved in accordance with this Section 12.1.

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## 12.2 Internal Resolution.

(a) The Parties shall negotiate in good faith and use reasonable efforts to settle any Dispute, controversy or claim arising from or related to this agreement or the breach thereof. If the Parties initially are unable to resolve a dispute despite using reasonable efforts to do so, either Party may, by written notice to the other, have the Dispute referred to the Executive Officers or their respective designees, for attempted resolution by negotiation in good faith; provided that disputes escalated to the Executive Officers by the JSC shall not be subject to additional rounds of escalation pursuant to this Section 12.2(a). The attempted resolution will take place no later than thirty (30) days following receipt of such notice. If the Parties are unable to resolve the dispute, controversy or claim within thirty (30) days following the day on which one Party provides written notice of the dispute to the other in accordance with this Section 12.2(a), and a Party wishes to pursue the matter, each such dispute, controversy or claim hereunder that is not an Excluded Claim (as defined below) will be finally resolved by mediation followed by binding arbitration as set forth below.

(b) **Mediation.** The Parties shall first attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current Mediation Procedure of the International Institute for Conflict Prevention and Resolution ("CPR Mediation Procedure") ([www.cpradr.org](http://www.cpradr.org)) before initiating arbitration. The CPR Mediation Procedure shall control, except where that procedure conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to the CPR Mediation Procedure. The mediation shall be held in New York, New York. Either Party may initiate mediation by written notice to the other of the existence of a Dispute. The Parties agree to select the mediator within twenty (20) days of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator or either Party declares in writing, no sooner than after the conclusion of one full day of a substantive mediation conference attended on behalf of each party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than sixty (60) days from the initial notice by a Party to initiate meditation unless the Parties agree in writing to extend that period. Any period of limitations set forth in this Section 12.1 that would otherwise expire between the initiation of mediation and its conclusion is extended until twenty (20) days after the conclusion of the mediation.

(c) **Arbitration.** If the parties fail to resolve the Dispute in mediation, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current CPR Rules for Non-Administered Arbitration of International Disputes ("CPR Rules") ([www.cpradr.org](http://www.cpradr.org)), except where they conflict with these provisions, in which case these provisions control. CPR is designated as the Neutral Organization for arbitration of all Disputes. The arbitration will be conducted in English and held in New York, New York. All aspects of the arbitration shall be treated as confidential. The arbitrators will be chosen from the CPR Panels of Distinguished Neutrals, unless a candidate not on the CPR Panel is approved by both Parties. Each arbitrator shall be a lawyer with expertise in the pharmaceutical industry and at least fifteen (15) years of experience with a law firm or corporate law department

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of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process. Prior to selection of the arbitrator(s), either Party may seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party until final resolution of the issue by the arbitrator or other resolution of the Dispute. The arbitration tribunal shall consist of three arbitrators, of whom each Party shall designate one (1) in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6. If, however, the aggregate award sought by the Parties is less than \$5 million and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules. The Parties agree to select the arbitrator(s) within forty-five (45) days of initiation of the arbitration. The hearing will be concluded within nine (9) months after selection of the arbitrator(s) and the award will be rendered within sixty (60) days of the conclusion of the hearing, or of any post hearing briefing, which briefing will be completed by both sides within forty-five (45) days after the conclusion of the hearing. In the event the parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practicable. Any final award by the arbitrator(s) may be entered by either Party in any court having appropriate jurisdiction for a judicial recognition of the decision and applicable orders of enforcement. Notwithstanding the foregoing, any Excluded Claim may be submitted by either Party to any court of competent jurisdiction over such Excluded Claim. For purposes of the foregoing, "Excluded Claim" means any dispute, controversy or claim that primarily concerns (a) the validity, enforceability or infringement or any patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

**12.3 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY [\*\*\*]. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.3 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY [\*\*\*].

## ARTICLE 13 MISCELLANEOUS

**13.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this

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Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**13.2 Governing Law; English Language.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws. The United Nations Conventions on Contracts for the International Sale of Goods shall not be applicable to this Agreement. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

**13.3 Rights in Bankruptcy.**

(a) If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code or similar provision in the bankruptcy laws of another jurisdiction (the “Code”), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to “intellectual property” as defined under Section 101(35A) of the Code (or similar provision in the bankruptcy laws of the jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code. Janssen and Theravance intend and agree that any sale of Theravance’s assets under Section 363(n) of the Code shall be subject to Janssen’s rights under Section 365(n), that Janssen cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser “free and clear” of Janssen’s rights under this Agreement and Section 365(n) without the express, contemporaneous written consent of Janssen. Further, each Party agrees and acknowledges that all payments by Janssen to Theravance hereunder, other than the Opt-In Exercise Fee and the royalty payments pursuant to Article 6, and the sales milestone payments pursuant to Section 6.5, do not constitute royalties within the meaning of Section 365(n) of the Code or relate to licenses of intellectual property hereunder. Theravance shall, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. Theravance and Janssen acknowledge and agree that “embodiments” of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data and Regulatory Materials. If (i) a case under the Code is commenced by or against Theravance, (ii) this Agreement is rejected as provided in the Code, and (iii) Janssen elects to retain its rights hereunder as provided in Section 365(n) of the Code, Theravance (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

(i) provide to Janssen all such intellectual property (including all embodiments thereof) held by Theravance and such successors and assigns, or otherwise available to them, immediately upon Janssen’s written request. Whenever Theravance or

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any of its successors or assigns provides to Janssen any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 13.3, Janssen shall have the right to perform Theravance's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by Janssen shall release Theravance from liability resulting from rejection of the license or the failure to perform such obligations; and

(ii) not interfere with Janssen's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

(b) The foregoing provisions of this Section 13.3 are without prejudice to any rights a Party may have arising under the Code, including the right of access to any intellectual property (including all embodiments thereof) of Theravance, or any Third Party with whom Theravance contracts to perform an obligation of Theravance under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of Products; and the right to contract directly with any Third Party to complete the contracted work.

**13.4 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the reasonable control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or machinery (*provided* that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than ninety (90) days, then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**13.5 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 13.5, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

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If to Theravance:

Theravance Biopharma Ireland Limited  
Connaught House  
1 Burlington Road  
Dublin 4 D04 C5Y6  
Ireland

Facsimile: [\*\*\*]

Attention: President

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

Theravance Biopharma US, Inc.  
901 Gateway Boulevard  
South San Francisco, CA 94080

Facsimile: [\*\*\*]

Attention: General Counsel

If to Janssen:

Janssen Biotech, Inc.  
800/850 Ridgeview Drive  
Horsham, PA 19044

Facsimile: [\*\*\*]

Attention: President

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

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

Facsimile: [\*\*\*]

Attention: General Counsel, Pharmaceuticals

**13.6 No Strict Construction; Headings.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in

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this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word “or” is used in the inclusive sense (and/or). The term “including” as used herein means including, without limiting the generality of any description preceding such term.

**13.7 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party’s consent to (a) its Affiliates (in whole or in part); or (b) a Third Party successor to all or substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other Change of Control transaction; provided that, in each case, if such assignment would reasonably be expected to cause adverse tax consequences to the non-assigning Party (or such Party’s Affiliates) and the assigning Party does not agree to bear full financial responsibility for such adverse tax consequences, such assignment shall not be made without the non-assigning Party’s consent (which consent shall not be unreasonably withheld), and the Parties shall reasonably cooperate to enable such assignment in a manner that avoids such adverse tax consequences. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing, expressly assume performance of such rights and/or obligations; provided that a Party assigning this Agreement and its rights and obligations hereunder to an Affiliate, shall remain responsible for the performance of such assignee Affiliate hereunder. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.7 shall be null, void and of no legal effect.

**13.8 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

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

**13.10 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

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**13.11 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**13.12 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Except as otherwise provided in Section 6.16(a), nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**13.13 Counterparts.** This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Executed counterpart signature pages delivered via facsimile or similar electronic transmission in .PDF or similar format shall be deemed binding as originals.

**13.14 Remedies Non-Exclusive and Cumulative.** Unless expressly stated otherwise in this Agreement, all remedies provided for in this Agreement shall be cumulative and in addition to, and not in lieu of, any other remedies available to either Party at law, in equity, or otherwise in accordance with the terms of this Agreement, including any claim for breach of this Agreement. Nothing in this Agreement shall be interpreted as limiting either Party's rights to pursue any remedies for breach of contract of this Agreement, except as expressly stated otherwise in this Agreement.

{Signature page follows}

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**IN WITNESS WHEREOF**, the Parties have executed this License and Collaboration Agreement by their duly authorized officers as of the Effective Date.

**JANSSEN BIOTECH, INC.**

**THERAVANCE BIOPHARMA IRELAND LIMITED**

By: /s/ Scott White

By: /s/ Ann Brady

Name: Scott White

Name: Dr. Ann Brady

Title: President, Immunology

Title: President, TBIL

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**LIST OF EXHIBITS:**

- Exhibit A – Theravance Patent Rights
- Exhibit B – Chemical Structure of TD-1473
- Exhibit C – Chemical Structure of TD-3504
- Exhibit D – [Reserved]
- Exhibit E – Initial Clinical Development Plan
- Exhibit F – Initial CMC Development Plan
- Exhibit G -- Phase 3 Development Budget
- Exhibit H – Data Policies
- Exhibit I – [Reserved]
- Exhibit J – [Reserved]
- Exhibit K – [Reserved]
- Exhibit L – J&J Universal Calendar
- Exhibit M – Financial Exhibit
- Exhibit N – Solar Patent Rights
- Exhibit O – Initial Budget for Pre-Opt-In Date Activities

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**EXHIBIT A**

**THERAVANCE PATENT RIGHTS**

[\*\*\*]

[\*\*\*]

| Country | Status | Application Number | Filing Date | Patent Number | Issue Date |
|---------|--------|--------------------|-------------|---------------|------------|
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       | [***]         | [***]      |
| [***]   | [***]  | [***]              | [***]       |               |            |

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| Country | Status | Application Number | Filing Date | Patent Number | Issue Date |
|---------|--------|--------------------|-------------|---------------|------------|
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |

N/A = Not yet available.

[\*\*\*]

[\*\*\*]

| Country | Status | Application Number | Filing Date | Patent Number | Issue Date |
|---------|--------|--------------------|-------------|---------------|------------|
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |
| [***]   | [***]  | [***]              | [***]       |               |            |

**See Exhibit K for Solar Patent Families as of the Effective Date**

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**EXHIBIT B**

**CHEMICAL STRUCTURE OF TD-1473**

**[\*\*\*]**

**TD-1473**

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**EXHIBIT C**

**CHEMICAL STRUCTURE OF TD-3504**

**[\*\*\*]**

**TD-3504**

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**EXHIBIT E**

**INITIAL CLINICAL DEVELOPMENT PLAN**

**1. Overview**

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

**2. Phase 2 Studies**

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

**3. Phase 2/3 Enabling Activities**

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

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#### 4. Planned Phase 3 Enabling Activities

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

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**EXHIBIT F**

**INITIAL CMC DEVELOPMENT PLAN**

**1. Overview**

[\*\*\*]

**2. Dose Assumptions for Clinical Studies**

[\*\*\*]

[\*\*\*]

[\*\*\*]

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[\*\*\*]

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**3. Manufacturing Plans**

[\*\*\*]

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[\*\*\*]

[\*\*\*]

[\*\*\*]

**4. Phase 3 Development Plans**

[\*\*\*]

[\*\*\*]

[\*\*\*]

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[\*\*\*]  
[\*\*\*]

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**EXHIBIT G**

**PHASE 3 DEVELOPMENT BUDGET**

**[\*\*\*]**

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## EXHIBIT H

### JANSSEN DATA GENERATION, PROCESSING AND STORAGE POLICIES

#### **1.0 Definitions:**

For this Exhibit only, the terms listed below shall have the meaning as defined below.

- 1.1 “**Data**” shall mean all data, including documentation, records, reports, raw data, processed data, deliverables, written, printed, graphic, video and audio recorded information contained in any computer database or computer readable form and work product of every kind and description supplied to or generated by or on behalf of a Party (the “**Data-Generating Party**”) as the result of performing activities under this Agreement.
- 1.2 “**Work Product**” shall mean the Data-Generating Party’s completed work product in accordance with the specifications set forth in this Agreement and any Data, reports, presentations, documents, computer models, deliverables or other results generated by or on behalf of the Data-Generating Party or supplied or delivered to the other Party by or on behalf of the Data-Generating Party under this Agreement.

#### **2.0 Data Generation and Processing:**

- 2.1 The Data-Generating Party represents and certifies that the Work Product, including all Data, will be collected and generated following the specifications contained in this Agreement and applicable industry standards.
- 2.2 The Data-Generating Party will use diligent efforts to ensure that the Data it provides is accurate, reliable and all results generated during the performance of services where feasible shall be reproducible and traceable. The Data-Generating Party must verify the Data during generation and prior to transfer of the Work Product with detailed notes of calculations applied and reasoning used for excluded data points.
- 2.3 The Data-Generating Party shall report all Data and its processing steps, decision-points, acceptance criteria, methods, calculations and results (complete and incomplete) to the other Party at mutually agreed upon points in time.
- 2.4 The Data-Generating Party shall keep a written or electronic notebook record of all activity associated with the performance of services under this Agreement, and shall make available the written records to the other Party at the completion of the services or upon request, and such records must document all data processing steps.
- 2.5 The Data-Generating Party shall collect, store and transfer electronic Data in accordance with the terms of this Agreement.

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2.7 No Data shall be destroyed by or on behalf of the Data-Generating Party without the prior written approval of the other Party for up to 2 years following completion of the Clinical Development Plan activities.

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**EXHIBIT L**

**J&J UNIVERSAL CALENDAR**

2018 UNIVERSAL CALENDAR

| M               | T | W  | T  | F  | S  | S  | M  | T  | W | T | F                | S  | S  |    |    |    |    |    |
|-----------------|---|----|----|----|----|----|----|----|---|---|------------------|----|----|----|----|----|----|----|
|                 |   | 1  | 2  | 3  | 4  | 5  | 6  | 7  |   |   | 2                | 3  | 4  | 5  | 6  | 7  | 8  |    |
| <b>JANUARY</b>  |   | 8  | 9  | 10 | 11 | 12 | 13 | 14 |   |   | <b>JULY</b>      | 9  | 10 | 11 | 12 | 13 | 14 | 15 |
| (4 Weeks)       |   | 15 | 16 | 17 | 18 | 19 | 20 | 21 |   |   | (4 Weeks)        | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|                 |   | 22 | 23 | 24 | 25 | 26 | 27 | 28 |   |   |                  | 23 | 24 | 25 | 26 | 27 | 28 | 29 |
|                 |   | 29 | 30 | 31 |    | 1  | 2  | 3  | 4 |   |                  | 30 | 31 |    |    |    |    |    |
| <b>FEBRUARY</b> |   |    |    |    | 1  | 2  | 3  | 4  |   |   | <b>AUGUST</b>    |    |    | 1  | 2  | 3  | 4  | 5  |
| (4 Weeks)       |   | 5  | 6  | 7  | 8  | 9  | 10 | 11 |   |   | (4 Weeks)        | 6  | 7  | 8  | 9  | 10 | 11 | 12 |
|                 |   | 12 | 13 | 14 | 15 | 16 | 17 | 18 |   |   |                  | 13 | 14 | 15 | 16 | 17 | 18 | 19 |
|                 |   | 19 | 20 | 21 | 22 | 23 | 24 | 25 |   |   |                  | 20 | 21 | 22 | 23 | 24 | 25 | 26 |
|                 |   | 26 | 27 | 28 |    |    |    |    |   |   |                  | 27 | 28 | 29 | 30 | 31 |    |    |
| <b>MARCH</b>    |   |    |    |    | 1  | 2  | 3  | 4  |   |   | <b>SEPTEMBER</b> |    |    |    |    |    | 1  | 2  |
| (5 Weeks)       |   | 5  | 6  | 7  | 8  | 9  | 10 | 11 |   |   | (5 Weeks)        | 3  | 4  | 5  | 6  | 7  | 8  | 9  |
|                 |   | 12 | 13 | 14 | 15 | 16 | 17 | 18 |   |   |                  | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|                 |   | 19 | 20 | 21 | 22 | 23 | 24 | 25 |   |   |                  | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
|                 |   | 26 | 27 | 28 | 29 | 30 | 31 |    |   |   |                  | 24 | 25 | 26 | 27 | 28 | 29 | 30 |
|                 |   |    |    |    |    |    |    | 1  |   |   |                  |    |    |    |    |    |    |    |
| <b>APRIL</b>    |   | 2  | 3  | 4  | 5  | 6  | 7  | 8  |   |   | <b>OCTOBER</b>   | 1  | 2  | 3  | 4  | 5  | 6  | 7  |
| (4 Weeks)       |   | 9  | 10 | 11 | 12 | 13 | 14 | 15 |   |   | (4 Weeks)        | 8  | 9  | 10 | 11 | 12 | 13 | 14 |
|                 |   | 16 | 17 | 18 | 19 | 20 | 21 | 22 |   |   |                  | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|                 |   | 23 | 24 | 25 | 26 | 27 | 28 | 29 |   |   |                  | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|                 |   | 30 |    |    |    |    |    |    |   |   |                  | 29 | 30 | 31 |    |    |    |    |
| <b>MAY</b>      |   |    | 1  | 2  | 3  | 4  | 5  | 6  |   |   | <b>NOVEMBER</b>  |    |    |    | 1  | 2  | 3  | 4  |
| (4 Weeks)       |   | 7  | 8  | 9  | 10 | 11 | 12 | 13 |   |   | (4 Weeks)        | 5  | 6  | 7  | 8  | 9  | 10 | 11 |
|                 |   | 14 | 15 | 16 | 17 | 18 | 19 | 20 |   |   |                  | 12 | 13 | 14 | 15 | 16 | 17 | 18 |
|                 |   | 21 | 22 | 23 | 24 | 25 | 26 | 27 |   |   |                  | 19 | 20 | 21 | 22 | 23 | 24 | 25 |
|                 |   | 28 | 29 | 30 | 31 |    |    |    |   |   |                  | 26 | 27 | 28 | 29 | 30 |    |    |
| <b>JUNE</b>     |   |    |    |    |    | 1  | 2  | 3  |   |   | <b>DECEMBER</b>  |    |    |    |    |    | 1  | 2  |
| (5 Weeks)       |   | 4  | 5  | 6  | 7  | 8  | 9  | 10 |   |   | (5 Weeks)        | 3  | 4  | 5  | 6  | 7  | 8  | 9  |
|                 |   | 11 | 12 | 13 | 14 | 15 | 16 | 17 |   |   |                  | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|                 |   | 18 | 19 | 20 | 21 | 22 | 23 | 24 |   |   |                  | 17 | 18 | 19 | 20 | 21 | 22 | 23 |
|                 |   | 25 | 26 | 27 | 28 | 29 | 30 |    |   |   |                  | 24 | 25 | 26 | 27 | 28 | 29 | 30 |
|                 |   |    |    |    |    |    |    | 1  |   |   |                  |    |    |    |    |    |    |    |

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## EXHIBIT M

### FINANCIAL EXHIBIT

Profit (Loss) in the U.S. shall be calculated in accordance with GAAP and this Exhibit. Profit (Loss) shall exclude the upfront payment (Section 6.1), the Opt-In Exercise Fee (Section 6.2) and the Milestone Payments (Section 6.4), all Development Costs and capital expenditures, and any other cost not specifically included in Allowable Expenses, including by way of example, [\*\*\*]. Cost items included in components of Profit (Loss) shall not be double counted and shall not be included in Development Costs. Profit (Loss) means the profits or losses resulting from the Commercialization of the Product in the U.S., which shall be equal to Net Sales less Allowable Expenses. Profit (Loss) in the U.S. shall be calculated for each Calendar Quarter. For the avoidance of doubt, income and withholding taxes imposed on either of the Parties or their Affiliates hereunder will not be included in the calculation of Profit (Loss).

#### **(1) Definitions**

The following definitions shall apply for purposes of calculating Profit (Loss) in accordance with this Financial Exhibit.

“Allowable Expenses” means the [\*\*\*].

“[\*\*\*]” means Out-of-Pocket Costs incurred by a Party in making any [\*\*\*] related to [\*\*\*] of the Product, including [\*\*\*]. “Cost of Goods Sold” or “COGS” means, with respect to a Product, a Party’s reasonable and necessary internal and Third Party invoiced costs, including Third Party contract manufacturing costs, determined in accordance with GAAP, incurred in manufacturing or acquisition of such Product. Manufacturing costs and acquisition costs are comprised of Standard Cost of Goods Manufactured, Cost Variances and Other Costs Not Included in Standard, where:

(a) “Standard Cost of Goods Manufactured” are budgeted unit costs established to facilitate inventory evaluation, planning and budgetary control, including but not limited to direct materials, direct labor, Third Party fees, product testing, transportation, depreciation of manufacturing, equipment and overhead;

(b) “Cost Variances” are actual costs of manufacturing versus Standard Cost of Goods Manufactured and include direct materials variances (including material usage variances and purchase price variances), direct labor variances and overhead variances (including but not limited to volume variances, variable overhead spending variances and fixed overhead spending variances); and

(c) “Other Costs Not Included in Standard” are actual costs of manufacturing which are incurred in the normal course of business but are not included in the Standard Cost of Goods Manufactured including cash discounts on raw material purchases, transportation expenses, manufacturing trial runs, manufacturing development expenses, start-up costs, material scrapped in the normal course of business (including failed commercial batches), full absorption adjustments, inventory revaluation adjustments, lower of cost or market inventory adjustments,

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inventory write-downs and write-offs, physical inventory adjustments, depreciation of equipment or instruments placed at customer or other Third Party sites, new product introduction costs, technical operations, internal inventory supply management, quality costs, returned goods, and supply point variances.

“[\*\*\*]” means [\*\*\*] of Net Sales in the U.S., which amount shall be deemed to have been incurred as [\*\*\*] in the U.S. It is understood that such amount shall be deemed to cover all costs identifiable to the [\*\*\*] in accordance with GAAP, which shall not otherwise be included in Allowable Expenses. For clarity, “[\*\*\*]” shall not include costs of activities included within [\*\*\*].

“[\*\*\*]” means Out-of-Pocket Costs and FTE Costs for activities conducted under the [\*\*\*]. Allowable Expenses set forth in the [\*\*\*] will be allocated [\*\*\*] to the U.S. and [\*\*\*] to the OUS Janssen Territory, unless otherwise agreed by the Parties. Such allocation will be updated by the Parties annually.

“[\*\*\*].” The [\*\*\*] will outline strategic [\*\*\*] that will be undertaken at the global team level that are intended to support [\*\*\*] activities across regions and key functions including pre-launch [\*\*\*].

“[\*\*\*]” means Out-of-Pocket Costs representing the [\*\*\*] and similar taxes and governmental fees in the U.S., in each case to the extent directly attributable to the Product, [\*\*\*], to the extent directly attributable to the Product, this shall also be included as an Allowable Expense.

“[\*\*\*]” means Out-of-Pocket Costs and FTE Costs identifiable to the [\*\*\*], in each case to the extent incurred specifically with respect to a Product (and to the extent not performed as part of a Detail), including:

- (a) [\*\*\*], which includes Out-of-Pocket Costs and FTE Costs associated with [\*\*\*] and meetings;
- (b) [\*\*\*], which includes Out-of-Pocket Costs and FTE Costs associated with [\*\*\*];
- (c) [\*\*\*], which includes Out-of-Pocket Costs and FTE Costs associated with [\*\*\*] and related Out-of-Pocket Costs;
- (d) [\*\*\*], which includes the FTE Costs of [\*\*\*], to the extent directly performing activities with respect to the [\*\*\*];
- (e) [\*\*\*], which includes Out-of-Pocket Costs incurred to manage [\*\*\*] directly attributable to a Product.

“[\*\*\*]” means Out-of-Pocket Costs and FTE Costs reasonably necessary and identifiable to a Product incurred with respect to any [\*\*\*].

“[\*\*\*]” means any Out-of-Pocket Costs and FTE Costs included in a [\*\*\*] that are not otherwise included in any other Allowable Expense category.

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

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“Profit (Loss)” means Net Sales in the United States less Allowable Expenses with respect to the United States.

“[\*\*\*]” means Out-of-Pocket Costs and FTE Costs directly associated with [\*\*\*] Product, [\*\*\*], in each case that are [\*\*\*]. The Parties acknowledge that [\*\*\*] associated with such recall shall not be included for determining whether the Party conducting [\*\*\*] to be incurred by such Party in such Calendar Year for Allowable Expenses.

“[\*\*\*]” means Out-of-Pocket Costs and FTE Costs for maintenance fees relating to [\*\*\*] for the Products in the Field in the U.S., personnel engaged in the filing and maintenance of [\*\*\*][\*\*\*].

“[\*\*\*]” means “fully burdened” costs and will cover employee salaries, bonus rate, and overhead allocated to such employee’s work including [\*\*\*] required for the portion of the [\*\*\*] that are assigned to such employee.

“[\*\*\*]” means all reasonable costs incurred by the Parties and their Affiliates that relate to [\*\*\*], in each case, solely to the extent [\*\*\*] sold by a Third Party or a product sold by a Third Party that [\*\*\*].

“[\*\*\*]” except with respect to such portion (if any) of costs related to [\*\*\*] prior to expiration of termination of the Agreement.

“[\*\*\*]” means Out-of-Pocket Costs representing reasonable [\*\*\*] (allocated as reasonably determined by the Finance Working Group), to [\*\*\*] of a Product in the U.S. and paid to [\*\*\*] to license or acquire such [\*\*\*] in the Field.

“Transfer Price” means the COGS of API or a finished Product supplied by Janssen or its Affiliates to Theravance or its Affiliates for commercial sale, or for API to be used in finished Product for commercial sale, in each case, plus [\*\*\*] of such COGS.

**(2) Reconciliations**

The Finance Working Group will coordinate to resolve any differences in or disputes regarding the calculation of Profit (Loss), or any component thereof. In the event the Finance Working Group is unable to resolve any such difference or dispute, the matter shall be resolved in accordance with Section 3.2.

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

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**EXHIBIT N**

**SOLAR PATENT RIGHTS**

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| Country | Status | Application Number | Filing Date | Patent Number | Issue Date |
|---------|--------|--------------------|-------------|---------------|------------|
| ***     | ***    | ***                | ***         |               |            |

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

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**EXHIBIT O**

**INITIAL BUDGET FOR PRE-OPT-IN DATE ACTIVITIES**

**[\*\*\*]**

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

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**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: May 9, 2018

/s/ Rick E Winningham

**Rick E Winningham**

Chairman of the Board and Chief Executive Officer  
(Principal Executive Officer)

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**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: May 9, 2018

/s/ Renee D. Gala

**Renee D. Gala**

Senior Vice President and Chief Financial Officer  
(Principal Financial Officer)

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