Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File No. 001-36033

THERAVANCE BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: **650-808-6000**

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange On Which Registered**
Ordinary Share $0.00001 Par Value	TBPH	The Nasdaq Global Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: **NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $1.28 billion, based upon the closing price of $20.99 on the Nasdaq Global Market on June 30, 2020.

On February 19, 2021, there were 64,327,830 of the registrant's ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2021 Annual Meeting of Shareholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

THERAVANCE BIOPHARMA, INC.
2020 Form 10-K Annual Report
Table of Contents

PART I

Special Note regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such forward-looking statements involve risks, uncertainties and assumptions. All statements in this Annual Report on Form 10-K, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, designs, expectations and objectives are forward-looking statements. The words "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "designed," "developed," "drive," "estimate," "expect," "forecast," "goal," "indicate," "intend," "may," "mission," "opportunities," "plan," "possible," "potential," "predict," "project," "pursue," "represent," "seek," "suggest," "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," in Item 1A, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 and elsewhere in this Annual Report on Form 10-K. Our forward-looking statements in this Annual Report on Form 10-K 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. In addition, while we expect the effects of COVID-19 to continue to adversely impact our business operations and financial results, the extent of the impact on our ability to generate revenue from YUPELRI® (revefenacin), our clinical development programs (including but not limited to our later stage clinical programs for izencitinib and ampreloxetine), and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. These potential future developments include, but are not limited to, the ultimate duration of the COVID-19 pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, other measures taken by us and those we work with to help protect individuals from contracting COVID-19, and the effectiveness of actions taken globally to contain and treat the disease, including vaccine availability, distribution, acceptance and effectiveness. When used in this report, all references to "Theravance Biopharma", the "Company", or "we" and other similar pronouns refer to Theravance Biopharma, Inc. collectively with its subsidiaries.

PART I

ITEM 1. BUSINESS

Overview

Theravance Biopharma, Inc. ("Theravance Biopharma" or the "Company") is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including the United States ("US") Food and Drug Administration (the "FDA") approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from Glaxo Group or one of its affiliates ("GSK") pursuant to its agreements with Innoviva, Inc. ("Innoviva") relating to certain programs, including TRELEGY.

2020 Highlights

Despite the delays and disruption caused by the COVID-19 pandemic, 2020 was a successful year in terms of progress as our key programs advanced towards important milestones.

YUPELRI Sales Growth

In the second full year since its commercial launch in the first quarter of 2019, YUPELRI continued to experience solid net sales growth in 2020. Through the combined commercialization efforts with our partner Viatris Inc. (formerly, Mylan N.V.), our collaboration revenue related to YUPELRI increased by 221% in 2020 compared to 2019. YUPELRI is the first and only once-daily, nebulized maintenance medicine for COPD. Theravance Biopharma and Viatris copromote in the US, with our combined sales infrastructures targeting health care professionals that treat the universe of COPD patients suitable for YUPELRI. Theravance Biopharma focuses on the hospital segment whereas Viatris focuses on the outpatient segment. While the COVID-19 pandemic impacted YUPELRI's sales growth trajectory in 2020, we saw sales growth recover in the second half of the year, and we continue to be encouraged by market feedback and performance indicators, including hospital formulary success, patient uptake, and market access, over the past 12 months.

Progression of Late-Stage Studies of Ampreloxetine and Izencitinib

Ampreloxetine, our norepinephrine reuptake inhibitor, continued to progress in two Phase 3 studies, one designed to assess treatment benefit over four weeks and the other to assess durability of response. Given limitations of existing neurogenic orthostatic hypotension ("nOH") treatments, ampreloxetine may represent an important treatment option for patients and a meaningful commercial opportunity in the US. To address the challenges presented by COVID-19, we modified our Phase 3 program to allow for a decentralized approach for treating patients in the trial. We anticipate reporting results on our Phase 3 clinical study of ampreloxetine in symptomatic nOH in the third quarter of 2021.

Izencitinib (formerly known as TD-1473), our oral gut-selective pan-JAK inhibitor for inflammatory intestinal diseases, partnered with Janssen Biotech, Inc. ("Janssen"), continued to progress in a Phase 2b/3 study in ulcerative colitis and a Phase 2 study in Crohn's disease. Izencitinib is intended to treat inflammatory intestinal disease directly at the site of inflammation in an organ-selective manner, with minimal systemic exposure or corresponding immunosuppressive effects. We anticipate reporting results from both studies in the third quarter of 2021.

Positive Phase 1 Data and Clinical Progression of TD-0903

TD-0903 is a lung-selective, nebulized Janus kinase inhibitor ("JAKi") in development for the potential treatment of hospitalized patients with Acute Lung Injury caused by COVID-19. We dosed our first patient in a Phase 1 study in April 2020 and results from that study in healthy volunteers showed a favorable safety and tolerability profile across the full range of nebulized doses and low systemic levels of TD-0903 in the systemic circulation, consistent with the lung-selective design. Data from Phase 1 provided confidence to continue dosing patients in a Phase 2 study, with results expected in the second quarter of 2021.

Advancement of TD-5202 into the Clinic

TD-5202, our oral gut-selective irreversible JAK3 inhibitor for inflammatory intestinal diseases, partnered with Janssen, continued to progress in the clinic. In the third quarter of 2019, we initiated a Phase 1 single ascending dose and multiple ascending dose study primarily designed to evaluate the safety and tolerability of TD-5202 in healthy subjects. In February 2020, we announced that data from the Phase 1 study indicated that TD-5202 was generally well tolerated as a single oral dose up to 2000 milligrams and as a twice-daily oral dose up 2000 milligrams total per day given for ten consecutive days in healthy subjects. We and our partner Janssen believe TD-5202 represents a promising additional therapeutic approach for addressing a range of inflammatory intestinal diseases.

Financing

We successfully closed on two financing transactions during the first quarter of 2020. In February 2020, we closed on an offering of 5,500,000 ordinary shares at a price to the public of $27.00 per share raising $148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses. Also, in February 2020, we closed on a private placement of $400.0 million of non-recourse Triple II 9.5% fixed rate term notes. The notes are secured by a portion of the future payments we expect to receive related to royalties due on net sales of TRELEGY. We used a portion of the net proceeds from this transaction to repay in full the remaining outstanding balance of the $250.0 million Triple PhaRMA^{SM} 9.0% fixed rate term notes due 2033. We are using the remainder of the net proceeds from both transactions to support continued execution of our key development programs.

Impact of COVID-19 Pandemic

The effects of the COVID-19 pandemic and the related actions by governments, companies, and individuals around the world to attempt to contain the spread of the virus (including new variants of COVID-19) continues to present a substantial public health and economic challenge and is affecting our employees, patients, communities, clinical trial sites, suppliers, business partners and business operations. The full extent to which the COVID-19 pandemic will continue to directly or indirectly impact our business, results of operations and financial condition, including revenue, expenses, clinical trials and research and development costs, will depend on future developments that are highly uncertain and may be impacted by the emergence of new information concerning the COVID-19 pandemic, ongoing spread of the disease across the US and the globe, and the actions taken to contain or treat the disease, including vaccine availability, distribution, acceptance and effectiveness.

YUPELRI (revefenacin) Inhalation Solution

We and our collaboration partner, Viatris, continue to supply YUPELRI to our patients and currently do not anticipate any interruptions in supply. The manufacture of YUPELRI continues at or near normal levels.

In mid-March 2020, we suspended in-person sales calls to accounts in response to the COVID-19 pandemic. Our promotional focus and efforts quickly pivoted to increased digital promotional investments and, in early August 2020, leveraging an optimized hybrid selling model with virtual and in-person selling interactions. While overall market challenges remain due to the ongoing COVID-19 pandemic, YUPELRI increased its market share and it was profitable on a stand-alone brand basis for the first time in the second half of 2020.

We continue to monitor the impact of the ongoing COVID-19 pandemic on demand for YUPELRI, including the duration and degree to which we may see declines in customer orders or delays in starting new patients on YUPELRI.

At this time, we are unable to predict with certainty the ultimate disruptive impact of the ongoing COVID-19 pandemic on both YUPELRI and the rest of our business, but we believe the pandemic may continue to put downward pressure on our sales to the extent that it continues to depress in-person customer interactions.

Clinical Trial Activity

While we are currently continuing the clinical trials that we had underway in sites across the globe prior to the onset of the pandemic, the timelines have been adversely impacted. We frequently evaluate each of our clinical trial programs to determine any additional necessary modifications and have worked closely with regulators, sites, clinical research organizations and data safety monitoring boards. Given the significant strains on the healthcare system across the globe, we made the decision in mid-March 2020 to temporarily suspend the screening of new patients for our clinical trials of izencitinib, a gut-selective oral JAKi in development for inflammatory intestinal disease in Crohn's and ulcerative colitis, and ampreloxetine, a norepinephrine reuptake inhibitor ("NRI") under evaluation for the treatment of symptomatic nOH, which are further discussed below. The screening of new patients into these trials was temporarily suspended for 4 weeks in order to prioritize ongoing support for patients who were already in screening and those who were already randomized. We implemented mitigation plans to help ensure patients in the clinical trials continued to have access to drug supply and regular visits with their physicians for study visits per trial protocols.

Screening of new patients resumed in mid-April 2020 in a controlled and measured fashion as individual sites confirmed their ability to support the study requirements, and new patients were able to be assessed for their eligibility to participate in the izencitinib and ampreloxetine studies. Study sites and necessary supporting medical infrastructure for our studies, such as endoscopy suites for our study of izencitinib in ulcerative colitis, have been gradually available for participation in and support of our trial through the year, increasing as cases dip and deceasing as cases surge. In recognition of the increasing range of barriers presented by the ongoing pandemic on the ability of nOH patients to travel to sites and access medicines, we worked with the FDA to decentralize the Phase 3 studies in the ampreloxetine program. We are working to offer the decentralized approach across the ampreloxetine Phase 3 program in the US and globally in an effort to overcome the challenges patients face regarding travel, healthcare access and participation in clinical trials. We currently expect Phase 3 results for ampreloxetine for symptomatic nOH and for izencitinib Phase 2b results in ulcerative colitis and Phase 2 results in Crohn's disease in the third quarter of 2021.

During the second quarter of 2020, we progressed our preclinical candidate TD-0903 into the clinic at an accelerated pace in response to the COVID-19 pandemic. We designed TD-0903 to be a lung-selective nebulized JAKi with the intent of addressing lung hyperinflammation in both the acute and chronic setting. In June 2020, we completed Phase 1 and entered a two-part Phase 2 study in the United Kingdom ("UK") to explore the potential of TD-0903 to treat hospitalized patients with Acute Lung Injury caused by COVID-19 and prevent progression to Acute Respiratory Distress Syndrome and the need for assisted ventilation. To expedite enrollment, we opened additional sites in other regions including Europe, US, South Africa and South America. We have completed Phase 2, Part 1 dose escalation and moved into Part 2. Phase 2, Part 2 is a randomized, double-blind, parallel-group study evaluating efficacy and safety of one dose (3 mg) of TD-0903 (selected based on the data from Part 1) as compared with placebo in 198 hospitalized patients with confirmed symptomatic COVID-19 who require supplemental oxygen. We expect to report results from the Phase 2, Part 2 study in the second quarter of 2021.

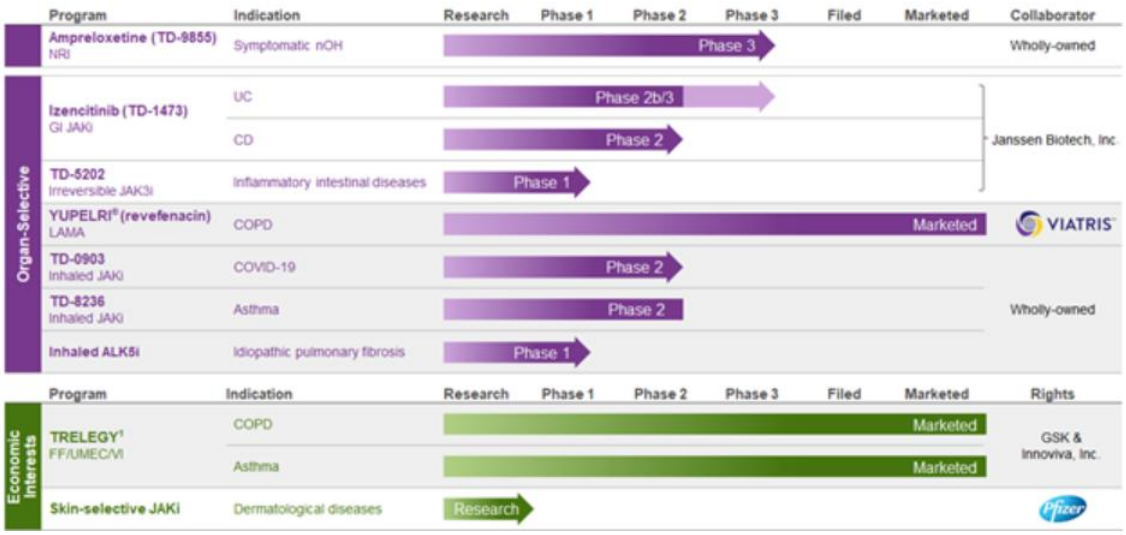
Business Operations

We continue to monitor the ongoing COVID-19 pandemic and plan to continue taking steps to identify and attempt to mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The threat of COVID-19 has caused us to modify our business practices, including implementing a work from home policy for all employees, with the exception of key operations and lab personnel, since early March 2020. We have restricted all non-essential business travel, and we expect to continue to implement measures as may be required or recommended by government authorities or as we

determine are in the best interests of our employees, clinical trial sites and participants, the patients we serve and other stakeholders in light of COVID-19.

Our Programs

The table below summarizes the status of our approved product and our other product candidates in development. The table also includes the status of the respiratory programs in which we have an economic interest and for which GSK is responsible pursuant to agreements between Innoviva and GSK ("GSK-Partnered Respiratory Programs"). These programs consist primarily of the TRELEGY program. We have an economic interest in these programs through our interest in Theravance Respiratory Company, LLC ("TRC"), a limited liability company managed by Innoviva. The status of all GSK-Partnered Respiratory Programs referenced in this Annual Report on Form 10-K are based solely upon publicly available information and may not reflect the most recent developments under the programs.



(1) We hold an 85% economic interest in upward-tiering royalty stream of 6.5% – 10% payable by GSK (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC Agreement over the next four fiscal quarters). 75% of TRC royalties received is pledged to service outstanding notes, and 25% of royalties received are retained by us. All statements concerning TRELEGY are based on publicly available information.

Glossary of Defined Terms used in Table Above:

COPD: Chronic Obstructive Pulmonary Disease;
CD: Crohn's Disease;
FF: Fluticasone Furoate;
JAKi: Janus Kinase Inhibitor;
LAMA: Long-Acting Muscarinic Antagonist;
nOH: Neurogenic Orthostatic Hypotension;
NRI: Norepinephrine Reuptake Inhibitor;
UC: Ulcerative Colitis;
UMEC: Umeclidinium; and
VI: Vilanterol

Program Highlights

YUPELRI (revefenacin) Inhalation Solution

YUPELRI (revefenacin) inhalation solution is a once-daily, nebulized long-acting muscarinic antagonist ("LAMA") approved for the maintenance treatment of COPD in the US. LAMAs are recognized by international COPD treatment guidelines as a cornerstone of maintenance therapy for COPD, regardless of severity of disease. 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. The stability of revefenacin in both metered dose inhaler and dry powder inhaler ("MDI/DPI") formulations suggests that revefenacin could also serve as a foundation for novel handheld combination products.

In November 2018, YUPELRI was approved by the FDA for the maintenance treatment of patients with COPD. Following shipments into commercial channel in late 2018, we and Viatris formally launched our sales and marketing efforts in early 2019. As described above and in *Item 1A. Risk Factor entitled "We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations,"* although YUPELRI net sales growth continued for the year ended December 31, 2020 compared to 2019, the trajectory was impacted by COVID-19, and we have observed increased volatility in YUPELRI sales. However, our YUPELRI operations were profitable on a brand basis for the first time in the second half of 2020. In addition, we are tracking several key performance metrics to gauge success in building market acceptance, including formulary success and market access.

Viatris Collaboration

In January 2015, Viatris and we established a strategic collaboration for the development and commercialization of revefenacin. Partnering with a 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. Viatris funded the Phase 3 development program of YUPELRI, enabling us to advance other high value pipeline assets alongside YUPELRI.

Under the terms of the Viatris Development and Commercialization Agreement (the "Viatris Agreement"), Viatris and we co-develop revefenacin for COPD and other respiratory diseases. We led the US Phase 3 development program for YUPELRI in COPD, and Viatris was 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 are shared. With YUPELRI approved in the US, Viatris is leading commercialization, and we co-promote the product in the US under a profit and loss sharing arrangement (65% to Viatris; 35% to Theravance Biopharma). Outside the US, Viatris is 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.

In June 2019, we announced the expansion of the Viatris Agreement to grant Viatris exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories, which include Hong Kong SAR, the Macau SAR, and Taiwan. In exchange, we received an upfront payment of $18.5 million (before a required tax withholding) and will be eligible to receive additional potential development and sales milestones totaling $54.0 million and low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. In March 2020, we earned a $1.5 million development milestone for the acceptance of a clinical trial application associated with the use of revefenacin monotherapy in China and adjacent territories. Viatris is responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration and all associated costs. We retain worldwide rights to revefenacin delivered through other dosage forms, such as a MDI/DPI.

Under the Viatris Agreement, as of December 31, 2020, we are eligible to receive from Viatris potential global development, regulatory and sales milestone payments totaling up to $257.5 million in the aggregate with $205.0 million associated with YUPELRI monotherapy and $52.5 million associated with future potential combination products. Of the $205.0 million associated with monotherapy, $187.5 million relates to sales milestones based on achieving certain levels of net sales and $17.5 million relates to global development and regulatory actions. The $52.5 million associated with future potential combination products relates solely to global development and regulatory actions.

Lung-selective, Nebulized Pan-Janus Kinase (JAK) Inhibitor (TD-0903)

TD-0903 is a lung-selective, nebulized Janus kinase inhibitor ("JAKi"), in clinical development for the potential treatment of hospitalized patients with Acute Lung Injury ("ALI") caused by COVID-19. We discovered TD-0903, and it has been shown in experimental murine models to have potent, broad inhibition of JAK-STAT signaling in the airways following challenges with multiple cytokines. Preclinical studies suggest that TD-0903 has a very high lung to plasma ratio and rapid metabolic clearance resulting in low systemic exposure, compatible with its lung selectivity. TD-0903 is administered via nebulized inhalation solution, which further enhances its lung selectivity. Preclinical pharmacodynamic studies indicate that TD-0903 has an extended duration of action that should enable once daily dosing in humans.

We believe TD-0903 has the potential to inhibit the cytokine storm associated with ALI and prevent progression to Acute Respiratory Distress Syndrome ("ARDS"). The first healthy volunteer was dosed in a Phase 1 study of TD-0903 in April 2020, and in June 2020, we completed Phase 1 and entered a two-part Phase 2 study. Phase 2 is designed to evaluate the efficacy, safety, and tolerability of TD-0903 in subjects with confirmed symptomatic COVID-19 hospitalized for symptomatic respiratory insufficiency. This study will also evaluate the PK of TD-0903 in these subjects. To expedite enrollment, we opened additional sites in other regions including Europe, the US, South Africa and South America.

We completed Phase 2, Part 1 a small sub-study of 25 patients intended to assess safety, PK and exploratory clinical measures of three doses of TD-0903 versus placebo. Data showed that inhaled administration of nebulized TD-0903, once daily over seven days, was generally well-tolerated and showed a numerical trend towards improved clinical status, reduced hospital stay and fewer deaths compared to placebo during a 28-day observation period. TD-0903 also demonstrated evidence of improvements in several relevant inflammatory biomarkers and low systemic exposure at all doses. This demonstrates the lung-selective design features of the molecule.

We have moved into Phase 2 Part 2, which is a randomized, double-blind, parallel-group study evaluating efficacy and safety of one dose (3 mg) of TD-0903 (selected based on the data from Part 1) as compared with placebo in 198 patients. We expect to report results from the Phase 2 Part 2 study in the second quarter of 2021.

Ampreloxetine (TD-9855)

Ampreloxetine is an investigational, once-daily norepinephrine reuptake inhibitor ("NRI") being developed for the treatment of patients with symptomatic neurogenic orthostatic hypotension ("nOH"). nOH is caused by primary autonomic failure conditions, including multiple system atrophy, Parkinson's disease and pure autonomic failure. The compound has high affinity for binding to norepinephrine transporters. By blocking the action of these transporters, ampreloxetine causes an increase in extracellular concentrations of norepinephrine. Ampreloxetine is wholly owned by us.

Based on positive top-line four-week results from a small exploratory Phase 2 study in nOH and discussions with the FDA, we advanced ampreloxetine into a Phase 3 program. The Phase 3 program includes two studies. The first study (SEQUOIA) is a four-week, randomized double-blind, placebo-controlled study designed to evaluate the efficacy and safety of ampreloxetine in patients with symptomatic nOH. The second study (REDWOOD) is a four-month open label study followed by a six-week randomized withdrawal phase to evaluate the durability of patient response of ampreloxetine. We announced the initiation of patient dosing in each Phase 3 study in early 2019. Phase 3 also includes a 26-week open-label study (OAK), which is a long-term extension study that will be ongoing at the time of registration, to allow participants completing REDWOOD to have continued access to ampreloxetine for up to 3.5 years and to collect safety and tolerability data over the course of treatment. As described above and in *Item 1A. Risk Factors*, the COVID-19 pandemic has impacted the timeline for our clinical trials. In recognition of the increasing range of barriers presented by the ongoing pandemic on the ability of patients to travel to sites and access medicines, we worked with the FDA to decentralize the Phase 3 studies in the ampreloxetine program. We are working to offer the decentralized approach across the ampreloxetine Phase 3 program in the US and globally in an effort to overcome the challenges patients face regarding travel, healthcare access and participation in clinical trials. We expect the SEQUOIA study to report data in the third quarter of 2021.

Gut-selective Pan-JAK Inhibitor Program (Izencitinib)

JAK inhibitors function by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) that play a key role in cytokine signaling. Inhibiting these JAK enzymes interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of a wide range of pro-inflammatory cytokines. JAK inhibitors are currently approved for the treatment of rheumatoid arthritis, myelofibrosis, and ulcerative colitis and have demonstrated therapeutic benefit for patients with Crohn's disease. However, these products are known to have side effects based on their systemic exposure. In izencitinib, our program goal is to develop an orally administered, gut-selective 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 believe izencitinib could be a potential treatment for a range of inflammatory intestinal diseases, and it is in development for the treatment of ulcerative colitis and Crohn's disease.

Based on positive results from a Phase 1b exploratory study in ulcerative colitis and following dialogues with the FDA and European Medicines Agency ("EMA") regarding study design, we advanced izencitinib into two clinical studies in inflammatory intestinal diseases. The Phase 2 (DIONE) study is a twelve-week randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of patients with Crohn's disease, which began dosing patients in late 2018. The Phase 2b/3 (RHEA) study is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of eight weeks induction and 44 weeks maintenance therapy in patients with ulcerative colitis, which began dosing patients in early 2019. As described above and in *Item 1A. Risk Factors*, the COVID-19 pandemic has impacted the timeline for our clinical trials. Data from the Phase 2b portion of the ulcerative colitis study and the Phase 2 Crohn's disease studies is expected in the third quarter of 2021.

Irreversible JAK3 Inhibitor (TD-5202)

TD-5202 is an investigational, orally administered, gut-selective, irreversible JAK3 inhibitor that has demonstrated a high affinity for the JAK3 enzyme. Through the selective inhibition of JAK3, TD-5202 interferes with the JAK/STAT signaling pathway and, in turn, modulates the activity of select pro-inflammatory cytokines, including IL-2, IL-15, and IL-21 which play a central role in the pathogenesis of T-cell mediated disease, including inflammatory intestinal disease, such as celiac disease. Importantly, TD-5202 is specifically designed to act locally within the intestinal wall thereby limiting systemic exposure.

In September 2019, we announced the initiation of a Phase 1 single ascending dose and multiple ascending dose trial designed to evaluate the safety and tolerability of TD-5202 in healthy participants, plus assess plasma pharmacokinetics of TD-5202 to confirm circulating levels are low, consistent with a gut-selective approach. In February 2020, we announced that data from the Phase 1 study indicated that TD-5202 was generally well tolerated as a single oral dose up to 2000 milligrams and as a twice-daily oral dose up 2000 milligrams total per day given for ten consecutive days in healthy participants.

We are developing izencitinib and TD-5202 in collaboration with Janssen as part of the companies' global co-development and commercialization agreement for novel, gut-selective JAK inhibitors.

Janssen Biotech Collaboration

In February 2018, we announced a global co-development and commercialization agreement with Janssen for izencitinib 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, inclusive of a potential opt-in payment following completion of the Phase 2 Crohn's study and the Phase 2b induction portion of the ulcerative colitis study. At that time, Janssen can elect to obtain an exclusive license to develop and commercialize izencitinib and certain related compounds by paying us a fee of $200.0 million. Upon such election, we and Janssen will jointly develop and commercialize izencitinib 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 Theravance Biopharma). In addition, we would receive royalties on ex-US sales at double-digit tiered percentage royalty rates.

The closing of the opt-in 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 izencitinib in Crohn's disease if it makes such an election. We will lead development of izencitinib in ulcerative colitis through completion of the Phase 2b/3 study. If izencitinib is commercialized, we have the option to co-commercialize in the US, and Janssen would have sole commercialization responsibilities outside the US.

Lung-selective Pan-JAK Inhibitor Program (TD-8236)

TD-8236 is an investigational, inhaled lung-selective pan-JAK inhibitor that has demonstrated a high affinity for each of the JAK family of enzymes (JAK1, JAK2, JAK3 and 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. While orally-administered JAK inhibitors are currently approved for the treatment of a range of inflammatory diseases, no inhaled JAK inhibitor is approved for the treatment of airway disease, including asthma. The pan-JAK activity of TD-8236 suggests that it may impact a broad range of cytokines that have been associated both T2-high and T2-low asthma. Many moderate to severe asthma patients comprising both T2 phenotypes remain symptomatic despite being compliant on high doses of inhaled steroids. Importantly, TD-8236 is designed to distribute and exert its anti-inflammatory effect within the lungs following dry powder inhalation, with the potential to treat inflammation within that organ while minimizing systemic exposure. In preclinical assessments, TD-8236 has shown to potently inhibit targeted mediators of T2-high and T2-low asthma in human cells.

In September 2019, we announced positive results from a Phase 1 single-ascending dose and multiple-ascending dose clinical trial of TD-8236. The Part C extension portion of the Phase 1 trial, assessing additional biomarkers in patients with moderate to severe asthma, demonstrated that biomarkers of JAK target engagement (including exhaled nitric oxide and pSTAT1 and pSTAT6 in cellular fractions of bronchoalveolar lavage fluid) were reduced after 7 days of once-daily dosing at a dose level of 1500 µg. In December 2019, we announced the initiation of a Phase 2 allergen challenge study of TD-8236 in mild allergic asthma patients, and we reported results of the Phase 1C study in the third quarter of 2020. TD-8236 is the first JAK inhibitor to be studied in a Phase 2a Lung Allergen Challenge ("LAC") study, but inconsistent with our expectations, it had no impact on decrease in lung function (FEV1) following allergen inhalation after 14 days of once-daily dosing at dose levels of 150 µg and 1500 µg compared to placebo and did not meet the primary study objective. The collective data set (preclinical, Phase 1, Phase 2a) demonstrates TD-8236 engages the JAK mechanism at a dose of 1500 µg as evidenced by the reduction in FeNO and reductions in pSTAT, but does not protect against the lung function decline seen after allergen inhalation.

After completing additional analysis on TD-8236 gene signature and biomarker data from the Phase 1C study, we found that the data are consistent with target engagement in the lung. However, based on our current understanding of TD-8236, we have decided to pause the clinical program for this specific compound in its current form and apply our learnings to refining and expanding molecules in our portfolio of inhaled JAK inhibitors. The robust body of scientific evidence from TD-8236 and TD-0903 programs provide confidence for us to continue the lung-selective inhaled JAK inhibitor program for asthma. The full data set for TD-8236 will be presented at future scientific meetings.

Economic Interest in GSK-Partnered Respiratory Programs

We hold an 85% economic interest in any future payments that may be made by GSK to Theravance Respiratory Company, LLC ("TRC") pursuant to its agreements with Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, which Innoviva partnered with GSK and assigned to TRC in connection with Innoviva's separation of its biopharmaceutical operations into its then wholly-owned subsidiary Theravance Biopharma in June 2014. The GSK-Partnered Respiratory Programs consists primarily of the TRELEGY program, which is 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 program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

TRELEGY (the combination of fluticasone furoate/umeclidinium bromide/vilanterol)

TRELEGY provides 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 is approved for use in the US and European Union ("EU") for the long-term, once-daily, maintenance treatment of patients with COPD. We hold an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) through our interest in TRC. Those royalties are upward-tiering from 6.5% to 10%, resulting in cash flows to us of approximately 5.5% to 8.5% of worldwide net sales of TRELEGY (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). Theravance Biopharma is not responsible for any of GSK's costs related to the development or commercialization of TRELEGY.

GSK and Innoviva conducted two global pivotal Phase 3 studies of TRELEGY in COPD, the IMPACT study and the FULFIL study. In September 2017, GSK and Innoviva announced that the FDA approved TRELEGY for the long-term, once-daily, maintenance treatment of appropriate patients with COPD. In August 2019, GSK announced that it had filed a supplemental new drug application ("sNDA") to the FDA supporting revised labelling for TRELEGY on reduction in risk of all-cause mortality compared with ANORO ELLIPTA in patients with COPD. The FDA postponed an Advisory Committee meeting that was previously scheduled for April 21, 2020 related to this sNDA which was subsequently rescheduled for August 31, 2020. During the FDA's Advisory Committee, the panel voted against the proposed all-cause mortality labeling claim. GSK announced during their third-quarter conference call on October 28, 2020 that the company received a Complete Response Letter from the FDA for the label update.

Additionally, GSK and Innoviva conducted a Phase 3 (CAPTAIN) study of TRELEGY in patients with asthma. In May 2019, GSK and Innoviva announced that the study had met its primary endpoint, and in October 2019, GSK announced it had filed a sNDA with the FDA seeking an additional indication for the use of once-daily, single-inhaler triple therapy, TRELEGY, for the treatment of asthma in adults. The FDA approved the asthma sNDA in September 2020 making TRELEGY the first once-daily single inhaler triple therapy for the treatment of both asthma and COPD in the US.

Theravance Respiratory Company, LLC

Prior to the June 2014 spin-off from Innoviva, our former parent company, 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.

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 (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). TRELEGY is currently the only commercial product arising out of the GSK agreements assigned by Innoviva to TRC. Royalty payments from GSK to TRC arising from the net sales of TRELEGY are presented in our consolidated statements of operations within "Income from investment in TRC, LLC" and is classified as non-operating income. During the three months ended June 30, 2020, we also recorded $8.5 million within "Income from investment in TRC, LLC" representing our share of a $10.0 million fee that GSK agreed to pay TRC upon termination of the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program in June 2020. Seventy-five percent of the "Income from investment in TRC, LLC," as evidenced by the Issuer II Class C Units (defined below), is available only for payment of the $400.0 million aggregate amount of 9.5% fixed rate non-recourse term notes due 2035 (the "Non-Recourse 2035 Notes") and is not available to pay our other obligations or the claims of our other creditors.

Our special purpose subsidiary Triple Royalty Sub II LLC (the "Issuer II") issued the Non-Recourse 2035 Notes in February 2020, the proceeds of which were used in part to repay the outstanding balance of our 9.0% non-recourse notes, due on or before 2033 (the "Non-Recourse 2033 Notes") that were issued in November 2018. The Non-Recourse 2035 Notes are secured by all of the Issuer II's rights, title and interest as a holder of certain membership

interests (the “Issuer II Class C Units”) in TRC. The Issuer II Class C Units entitle the Issuer II to receive 63.75% of the economic interest that TRC receives in any future payments made by GSK under the agreements described above, or 75% of the income from our 85% ownership interest in TRC.

On June 10, 2020, we disclosed in a Form 8-K that we had formally objected to TRC and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to us under the terms of the TRC LLC Agreement. We intend to continue to seek to protect our interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, we initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to us in a manner consistent with the TRC LLC Agreement and our 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the first quarter or early in the second quarter of 2021.

Other Economic Interests

Selective 5-HT4 Agonist (TD-8954)

TD-8954 is a selective 5-HT4 receptor agonist being developed for potential use in the treatment of gastrointestinal motility disorders.

Takeda Collaborative Arrangement

In June 2016, we entered into a License and Collaboration Agreement (the “Takeda Agreement”) with Millennium Pharmaceuticals, Inc. (“Millennium”), in order to establish a collaboration for the development and commercialization of TD-8954 (TAK-954). Millennium is an indirect wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”). TD-8954 is currently in a Phase 2 study as a potential treatment for post-operative gastrointestinal dysfunction. Under the terms of the Takeda Agreement, Takeda is 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 from Takeda. 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.

Skin-selective Pan-JAK inhibitor program

In December 2019, we entered into a global license agreement with Pfizer Inc. (“Pfizer”) for our preclinical skin-selective, locally-acting pan-JAK inhibitor program (the “Pfizer Agreement”). The compounds in this program are designed to target validated pro-inflammatory pathways and are specifically designed to possess skin-selective activity with minimal systemic exposure.

Under the Pfizer Agreement, Pfizer has an exclusive license to develop, manufacture and commercialize certain compounds for all uses other than gastrointestinal, ophthalmic and respiratory applications. We received an upfront cash payment of $10.0 million and are eligible to receive up to an additional $240.0 million in development and sales milestone payments from Pfizer. In addition, we are eligible to receive a tiered royalty on worldwide net sales of any potential products under the license at percentage royalty rates ranging from middle single-digits to low double-digits.

Research Projects

Our research goal is to design organ-selective medicines that target diseased tissues, without systemic exposure, in order to maximize patient benefit and minimize risk. The intention is to expand the therapeutic index of our potential medicines compared to conventional systemic therapies. Our efforts leverage years of experience in developing lung-selective medicines, such as YUPELRI, to treat respiratory diseases, and have led to the discovery of the gut-selective pan-JAK inhibitor izencitinib and irreversible JAK3 inhibitor TD-5202 for inflammatory intestinal diseases and the lung-selective inhaled JAK inhibitor TD-8236 and nebulized pan JAK inhibitor TD-0903 in serious respiratory disease. We plan to advance towards the clinic other research projects with various mechanisms of action, each specifically tailored for the organ of interest, as we identify and validate potentially appropriate compounds. Our research is focused

in the areas of inflammation and immunology, and our pipeline of internally discovered programs is targeted to address significant patient needs.

Our Strategy

Our core purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. We strive to apply insight and innovation at each stage of our business, including research, development and commercialization. Our principle strategic objective is to transform the treatment of serious diseases through the discovery, development, and commercialization of organ-selective medicines designed to maximize patient benefit while minimizing patient risk.

We follow these core guiding principles in our mission to drive value creation:

- Focus on insight and innovation;
- Outsource non-core activities;
- Create and foster an integrated environment; and
- Aggressively manage uncertainty.

We manage our pipeline with the goal of optimizing program value and allocation of resources. We employ multiple strategies for commercialization of our products. Our approach may involve retaining product rights and marketing a product independently in the US or we may partner a product to extend our commercial reach, to expand our geographic reach, and/or to manage the financial risk associated with the program. Alternatively, we may monetize or divest an asset that we designate as outside our core business, where we believe the program is optimized by leveraging partner capabilities and removing or limiting our research and development costs.

Manufacturing

We rely primarily on a network of third-party manufacturers, including contract manufacturing organizations, to produce the active pharmaceutical ingredients ("API") and drug products required for our clinical trials and drug product. We believe that we and our partners have in-house expertise to manage this network of third-party manufacturers, and we believe that we will be able to continue to negotiate third-party manufacturing arrangements on commercially reasonable terms and that it will not be necessary for us to rely on internal manufacturing capacity in order to develop or, potentially, commercialize our products. However, if we are unable to obtain contract manufacturing or obtain such manufacturing on commercially reasonable terms, or if manufacturing is interrupted at one of our suppliers, whether due to regulatory or other reasons, we may not be able to develop our products or commercialize product as planned.

Any inability to acquire sufficient quantities of API or drug product in a timely manner from current or future sources could disrupt our research and development programs, the conduct of future clinical trials or our commercialization efforts. For more information, see the risk factor under the heading "*There is a single source of supply for a number of our product candidates and for YUPELRI, 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*" of this Annual Report on Form 10-K.

Government Regulation

The development and commercialization of pharmaceutical products and our product candidates by us, our collaboration partners and licensees, GSK, and Cumberland Pharmaceuticals Inc. ("Cumberland") and our ongoing research are subject to extensive regulation by governmental authorities in the US and other countries. Before marketing in the US, any medicine must undergo rigorous preclinical studies and clinical studies and an extensive regulatory approval process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act. Outside the US, the ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities which are subject to equally rigorous regulatory obligations. The requirements governing the conduct of clinical studies,

marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, the commercialization of pharmaceutical products is permitted only if the appropriate regulatory authority is satisfied that we have presented adequate evidence of the safety, quality and efficacy of the product.

Before commencing clinical studies in humans in the US, we must submit to the FDA an investigational new drug application ("IND") that includes, among other things, the general investigational plan and protocols for specific human studies and the results of preclinical studies. An IND will go into effect 30 days following its receipt by the FDA unless the FDA issues a clinical hold. Once clinical studies have begun under the IND, they are usually conducted in three phases and under FDA oversight. These phases generally include the following:

Phase 1. The product candidate is introduced into patients or healthy human volunteers and is tested for safety, dose tolerance and pharmacokinetics.

Phase 2. The product candidate is introduced into a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks.

Phase 3. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase 2 evaluations, the clinical study will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population.

The results of product development, preclinical studies and clinical studies must be submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. The Prescription Drug User Fee Act ("PDUFA") establishes timeframes for FDA review of NDAs, with a performance goal of reviewing and acting on 90 percent of priority new molecular entity ("NME") NDA submissions within 6 months of the 60-day filing date, and to review and act on 90 percent of standard NME NDA submissions within 10 months of the 60-day filing date. The 2007 Food and Drug Administration Amendments Act gave the FDA authority to require implementation of a formal Risk Evaluation and Management Strategy to ensure that the benefits of a product outweigh its risks. At the end of the review period, the FDA communicates either approval of the NDA or a complete response listing the application's deficiencies.

Once approved, the FDA may withdraw the product approval if compliance with post-marketing regulatory standards is not maintained or if safety or quality issues are identified after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, sometimes referred to as Phase 4 studies, to monitor the safety and effectiveness of approved products, and may limit further marketing of the product based on the results of these post-marketing studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize products, withdraw approvals, enjoin violations, and initiate criminal prosecution.

If regulatory approval for a medicine is obtained, the clearance to market the product will be limited to those diseases and conditions approved by FDA and for which the medicine was shown to be effective, as demonstrated through clinical studies and specified in the medicine's labeling. Even if this regulatory approval is obtained, a marketed medicine, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The FDA ensures the quality of approved medicines by carefully monitoring manufacturers' compliance with its current Good Manufacturing Practice ("cGMP") regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a medicine. The regulations are intended to make sure that a medicine is safe for use, and that it has the ingredients and strength it claims to have. Discovery of previously unknown problems with a medicine, manufacturer or facility may result in restrictions on the medicine or manufacturer, including costly recalls or withdrawal of the medicine from the market.

We, our collaboration partners and licensees are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to suspend or delay issuance of approvals, seize

products, withdraw approvals, enjoin violations, and initiate criminal prosecution, any one or more of which could have a material adverse effect upon our business, financial condition and results of operations.

Outside the US our, our collaboration partners', licensees', GSK's and Cumberland's ability to market products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. Risks similar to those associated with FDA approval described above exist with the regulatory approval processes in other countries.

United States Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together the "Healthcare Reform Act"), substantially changed the way healthcare is financed by both governmental and private insurers, and impacts pricing and reimbursement of YUPELRI and the marketed drugs with respect to which we are entitled to royalty or similar payments, and related commercial operations. Certain provisions of the Healthcare Reform Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. We expect that the Healthcare Reform Act, its implementation, efforts to repeal or replace, or invalidate, the Healthcare Reform Act or portions thereof, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of our existing products or to successfully commercialize our product candidates, if approved. For more information, see the risk factor under the heading *"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 us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties"* of this Annual Report on Form 10-K.

Pharmaceutical Pricing and Reimbursement

We participated in and had certain price reporting obligations under the Medicaid Drug Rebate program for VIBATIV for which we remain responsible, as described in greater detail under the risk factor "*If we failed 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"* of this Annual Report on Form 10-K.

Our ability, and the ability of our collaboration partners, licensees, or those commercializing products with respect to which we have an economic interest or right to receive royalties to commercialize our products successfully, and our ability to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the US, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. The reimbursement environment is described in greater detail under the risk factor *"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 us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties"* of this Annual Report on Form 10-K.

Fraud and Abuse Laws

Our interactions and arrangements with customers and third-party payors are subject to applicable US federal and state fraud and abuse laws and equivalent third country laws. These laws and the related risks are described in greater detail under the risk factor "*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*" of this Annual Report on Form 10-K.

Data Privacy and Protection

We are subject to 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 and/or genetic privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act ("FTC Act")), govern the collection, use, disclosure, and protection of health-related and other personal information. Similar obligations apply outside of the US. For example, the General Data Protection Regulation ("GDPR") which entered into force on May 25, 2018 amplified existing data protection obligations in the EU. These laws and related risks are described in greater detail under the risk factor "*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*" of this Annual Report on Form 10-K.

Patents and Proprietary Rights

We will be able to protect our technology from unauthorized use by third parties only to the extent that our technology is covered by valid and enforceable patents or is effectively maintained as trade secrets. Our success in the future will depend in part on obtaining patent protection for our product candidates. Accordingly, patents and other proprietary rights are essential elements of our business. Our policy is to seek in the US and selected foreign countries patent protection for novel technologies and compositions of matter that are commercially important to the development of our business. For proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery process that involve proprietary know-how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements to protect our interests. We require all of our employees, consultants and advisors to enter into confidentiality agreements. Where it is necessary to share our proprietary information or data with outside parties, our policy is to make available only that information and data required to accomplish the desired purpose and only pursuant to a duty of confidentiality on the part of those parties.

As of December 31, 2020, we owned 507 issued US patents and 2,253 granted foreign patents, as well as additional pending US patent applications and foreign patent applications. The claims in these various patents and patent applications are typically directed to compositions of matter, including claims covering product candidates, crystalline forms, lead compounds and key intermediates, pharmaceutical compositions, methods of use and/or processes for making our compounds. In particular, our wholly-owned subsidiary Theravance Biopharma R&D IP, LLC owns the following US patents which are listed in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for YUPELRI (revefenacin) inhalation solution: US Patent No. 7,288,657, expiring on December 23, 2025; US Patent No. 7,491,736, expiring March 10, 2025; US Patent No. 7,521,041, expiring March 10, 2025; US Patent No. 7,550,595, expiring March 10, 2025; US Patent No. 7,585,879, expiring March 10, 2025; US Patent No. 7,910,608, expiring March 10, 2025; US Patent No. 8,034,946, expiring March 10, 2025; US Patent No. 8,053,448, expiring March 10, 2025; US Patent No. 8,273,894, expiring March 10, 2025; US Patent No. 8,541,451, expiring August 25, 2031; US Patent No. 9,765,028, expiring July 14, 2030; US Patent No. 10,106,503, expiring March 10, 2025; US Patent No. 10,343,995, expiring March 10, 2025; and US Patent No. 10,550,081, expiring July 14, 2030 (each of the aforementioned expiration dates not including any patent term extensions that may be available under the Drug Price Competition and Patent Term Restoration Act of 1984). Thus, the last to expire patent currently listed in the Orange Book for YUPELRI (revefenacin) inhalation solution expires on August 25, 2031. On December 19, 2018, we filed patent term extension ("PTE") applications in the US Patent and Trademark Office ("USPTO") for US Patent Nos. 7,288,657 and 7,585,879. These PTE applications are currently pending and if granted, we will be permitted to extend the term of one of these patents for the period determined by the USPTO.

Issued US and foreign patents generally expire 20 years after their filing date. The patent rights relating to YUPELRI (revefenacin) inhalation solution currently consist of issued US patents, pending US patent applications and counterpart patents and patent applications in a number of jurisdictions, including Europe. Additionally, our patent rights relating to ampreloxetine and izencitinib currently include issued US composition of matter patents that expire in 2030 and 2036, respectively (not including any patent term extensions that may be available under the Drug Price Competition and Patent Term Restoration Act of 1984), as well as additional issued US patents, pending US patent applications and/or counterpart patents and patent applications in a number of jurisdictions. Nevertheless, issued patents can be

challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products and threaten our ability to commercialize our product candidates. Our patent position, similar to other companies in our industry, is generally uncertain and involves complex legal and factual questions. To maintain our proprietary position, we will need to obtain effective claims and enforce these claims once granted. It is possible that, before any of our products can be commercialized, any related patent may expire or remain in force only for a short period following commercialization, thereby reducing any advantage of the patent. Also, we do not know whether any of our patent applications will result in any issued patents or, if issued, whether the scope of the issued claims will be sufficient to protect our proprietary position.

Competition

Our late-stage development programs, and the marketed products to which we are entitled to profit share revenue, royalty or similar payments, primarily target three therapeutic areas— respiratory, gastrointestinal, and neurological. In research, we apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. Our commercial infrastructure is focused primarily on the acute care setting. We expect that any medicines that we commercialize with our collaborative partners or on our own will compete with existing and future market-leading medicines.

Many of our 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, development and commercialization to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified scientific, clinical development and commercial personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- commercialize approved products; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

YUPELRI (revefenacin) inhalation solution, a long-acting muscarinic antagonist (LAMA)

YUPELRI competes predominately with the nebulized LAMA Lonhala® Magnair® (glycopyrrolate) dosed two times per day and with short acting nebulized bronchodilators that are dosed three to four times per day.

TRELEGY or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)

For treatment of COPD, TRELEGY competes in the US with AstraZeneca's Breztri® Aerosphere® (budesonide/glycopyrronium/formoterol fumarate, dosed twice per day). Breztri was approved for COPD by EMA in December 2020 and is expected to launch in 2021. Trimbow (beclometasone dipropionate/formoterol fumarate/glycopyrronium bromide, dosed twice per day) from Chiesi Farmaceutici is an additional COPD competitor in Europe. TRELEGY also competes with Breztri in Japan and China for COPD.

For treatment of asthma, TRELEGY is the only triple therapy approved in the US and competes in Japan with Novartis's Enerzair® Breezhaler® (indacaterol acetate, glycopyrronium bromide and mometasone furoate, dosed once daily). Enerzair and Trimbow are currently under review by EMA, and, if approved in Europe they will compete with TRELEGY.

In both COPD and asthma, TRELEGY also competes with “open triple” therapy which can be accomplished by the concurrent use of two or three products. An example of such use includes a LABA/ICS combination such as AstraZeneca’s Symbicort and a LAMA such as Boehringer Ingelheim’s Spiriva.

Gut-selective Pan-JAK Inhibitor Program (Izencitinib)

If successfully developed and approved, izencitinib would be expected to compete with biologics, which have become the mainstay of treatment in moderate-to-severe IBD patients, steroids, immunosuppressants, and other JAK inhibitors (all of which provide systemic exposure and are, thus, not gut-selective). Biologics for treatment of IBD (all of which require intravenous or sub-cutaneous administration) include the anti-TNF monoclonal antibodies Humira® (adalimumab), marketed by AbbVie Inc., and Remicade® (infliximab), marketed by Janssen Pharmaceuticals, Inc., and the anti-integrin antibody Entyvio® (vedolizumab), marketed by Takeda Pharmaceuticals America, Inc. Pfizer Inc.’s Xeljanz® (tofacitinib) was the first systemic JAK inhibitor approved by the FDA for the treatment of ulcerative colitis, although other systemic JAK inhibitors are currently in clinical development for IBD including filgotinib (Gilead Sciences, Inc.) and upadacitinib (AbbVie Inc.).

Ampreloxetine norepinephrine reuptake inhibitor (“NRI”)

If successfully developed and approved, ampreloxetine would be expected to compete predominantly with Northera® (droxidopa) marketed by Lundbeck NA Ltd., and to a lesser extent, midodrine and fludrocortisone which are available as generics. In addition, generic droxidopa is expected to enter the US market in February 2021 following expiration of the orphan drug exclusivity for Northera®.

Human Capital

As of December 31, 2020, we had 359 employees. Of these employees, 331 were in the US and 28 were non-US.

Our ability to sustain and grow our business requires us to hire, retain and develop a highly skilled and diverse workforce. We emphasize the importance of character and integrity as much as professional qualifications, and we seek to foster a culture of empowerment where employees have ownership in business outcomes. We strive to keep our people engaged and working collaboratively with an understanding that behaviors that matter are reflected in our Core Values - *thinking it through, finding a way, getting it done, and winning together.* Our employees are encouraged through many forms of corporate communication such as an open-door policy, all employee meetings, an anonymous online suggestion box, and an Employee Pulse Survey, to ask questions, make suggestions, and provide input.

Diversity and Inclusion

We strive to build a culture of diversity and inclusion through our business and human resources practices and policies, and we work to eliminate discrimination and harassment in all of its forms, including related to color, race, sex or gender, sexual orientation, gender identity, age, pregnancy, caste, disability, ethnicity, national origin or ancestry, religious beliefs, veteran status, uniformed servicemember status, or physical or mental disability. We have both a Diversity & Inclusion Council and a Women’s Leadership Network, which are each Company-sponsored, employee-led groups that aim to improve attraction, retention, development, inclusion, and engagement of a diverse and global workforce.

Talent Acquisition and Retention

We believe that our philosophy of providing competitive compensation and benefits and our focus on providing opportunities for career growth and development fosters interest from external candidates in Company openings, increases Company employee tenure, and reduces voluntary employee turnover. The global acceptance rate of our employment offers is consistently high. We believe we are successful in our retention efforts because we provide challenging work assignments, cross functional teamwork experiences and career progression supported by new skill building. We invest in employee learning and development by identifying and providing training and development programs, speakers, and other materials and have personnel specifically focused on employee learning and development. Based upon informal and formal feedback, including our Employee Pulse Surveys, management’s relationship with

employees is very good. Because retention of the employee base is key to our business strategy, executive management provides quarterly updates on turnover metrics to our board of directors.

Total Rewards

We reward our employees beyond a competitive base salary. Our employees also receive cash bonus opportunities, equity incentives, health and wellness benefits and programs, and educational benefits. We strive to offer a competitive total rewards package that is responsive to market needs based upon the specific requirements of the job. Some examples of benefits offered include:

- quality, affordable health insurance coverage available to both full-time and part-time employees and their eligible dependents;
- matching contributions to a tax-qualified defined contribution savings ("401k") plan, on a dollar-for-dollar basis up to a set dollar amount of an employee's cash compensation;
- an employee stock purchase plan ("ESPP"); and
- training and development programs designed to support and improve workplace performance.

Culture

We expect all employees to observe the highest levels of business ethics, while also delivering the highest levels of performance. These expectations are set forth in various documents and forms of communication within and across our Company. The Company encourages employees to speak up and raise questions and concerns promptly about any situation that may violate our Code of Business Conduct, our core values or our policies. We believe that it benefits the entire Company for employees to raise concerns so the Company may consider them carefully and address them properly. We seek to promote an environment that fosters honest communications about matters of conduct related to our business activities, whether that conduct occurs within the Company, involves one of the Company's contractors, suppliers, consultants, or clients, or involves any other party with a business relationship with the Company. We work to make clear that management is prepared to address any reported violations and to ensure that it is known that any form of retaliation is strictly prohibited. In addition, we have an easily-accessible hotline available to employees wishing to report complaints anonymously.

Financial Information About Geographic Areas

Information on our total revenues attributed to geographic areas and customers who represented at least 10% of our total revenues is included in "*Item 8, Note 4. Segment Information,*" to our consolidated financial statements in this Annual Report on Form 10-K.

Corporation Information

Theravance Biopharma was incorporated in the Cayman Islands in July 2013 under the name Theravance Biopharma, Inc. Theravance Biopharma began operating as an independent, publicly-traded company on June 2, 2014 following a spin-off from Innoviva, Inc. Our corporate address in the Cayman Islands and principal executive office is P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands and the address of our wholly-owned US operating subsidiary Theravance Biopharma US, Inc. is 901 Gateway Boulevard, South San Francisco, California 94080. While Theravance Biopharma is incorporated under Cayman Island law, the Company became an Irish tax resident effective July 1, 2015. The address of our wholly-owned Irish operating subsidiary, Theravance Biopharma Ireland Limited, is Connaught House, Burlington Road, Dublin 4, Ireland.

Available Information

Our Internet address is *www.theravance.com*. Our investor relations website is located at *http://investor.theravance.com*. We make available free of charge on our investor relations website under "SEC Filings" our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our directors' and officers' Section 16 Reports and any amendments to those reports as soon as reasonably practicable after filing or

furnishing such materials to the US Securities and Exchange Commission ("SEC"). Our current Code of Business Conduct, Corporate Governance Guidelines, Articles of Association, Board of Director Committee Charters, and other materials, including amendments thereto, may also be found on our investor relations website under "Corporate Governance." The information found on our website is not part of this or any other report that we file with or furnish to the SEC. Theravance Biopharma and the Theravance Biopharma logo are registered trademarks of the Theravance Biopharma group of companies. Trademarks, tradenames or service marks of other companies appearing in this report are the property of their respective owners.

ITEM 1A. RISK FACTORS

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.

Summary of Principal Risks Associated with Theravance Biopharma's Business

- We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability;
- We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of 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;
- If our product candidates are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them;
- If additional capital is not available, we may have to curtail 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;
- 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 do not control TRC and, in particular, have no control over the GSK Partnered Respiratory Programs, including TRELEGY, or access to non-public information regarding the development of the GSK Partnered Respiratory Programs;
- 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, our business will be harmed, and the price of our securities could fall; and
- Our ongoing drug discovery and development efforts might not generate additional successful product candidates or approvable drugs.

RISKS RELATING TO THE COMPANY

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 year ended December 31, 2020, 2019, and 2018, we recognized net losses of $278.0 million, $236.5 million and $215.5 million, respectively, which are reflected in the shareholders' deficit 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, which was $1.5 billion as of December 31, 2020. 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 YUPELRI. In particular, to the extent we continue to advance our product candidates into and through additional clinical studies, we will incur substantial expenses. For example, we initiated a Phase 2b/3 induction and maintenance study of izencitinib in ulcerative colitis, we initiated a Phase 2 induction study of izencitinib in Crohn's disease, and we have progressed ampreloxetine (TD-9855) into a Phase 3 registrational program. The expenses associated with these clinical studies are substantial. While our YUPELRI operations were profitable on a brand basis for the second half of 2020, we will continue to incur costs and expenses associated with the commercialization of YUPELRI in the United States ("US"), including the maintenance of an independent sales and marketing organization with appropriate technical expertise, a medical affairs presence and consultant support, and post-marketing studies. Our commitment of resources to the continued development of our existing product candidates, our discovery programs, and YUPELRI 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;
- our clinical trials become more complicated due to the COVID-19 pandemic or other similar external factors;
- 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.

While we are generating revenues from (i) sales of YUPELRI, (ii) our economic interest in royalties from net sales of TRELEGY paid to TRC (63.75% of which amounts are used to make payments on the Non-Recourse 2035 Notes), (iii) payments under collaboration agreements, and (iv) minor royalties from the net sales of VIBATIV, we do not expect to generate significant revenues or become profitable in the near future. As a result of the COVID-19 pandemic (defined below), we could experience declines in revenues from these sources. 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 will continue to exceed any revenues we may receive for the foreseeable future.

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 those 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.

We face risks related to health epidemics, including the recent COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Our business has been and will continue to be adversely affected by the recent widespread and contagious outbreak of respiratory illness caused by a novel strain of coronavirus, SARS-CoV-2, causing the Coronavirus Disease 2019, also known as COVID-19 (the "COVID-19 pandemic"). Global health concerns relating to the COVID-19 pandemic have been weighing on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns. These measures have adversely impacted and may further impact our employees and operations and the operations of our customers, suppliers and business partners, and may negatively impact spending patterns, payment cycles and insurance coverage levels. In addition, certain aspects of our business, such as laboratory-based research, cannot be conducted remotely and other aspects of our business, like our hospital-based sales team, our field-based medical affairs team, and our support of sites in our clinical trials, cannot be accomplished as effectively or efficiently remotely. These measures by government authorities, as well as the precautions we will take in order to operate our business responsibly in light of the COVID-19 pandemic, may continue to remain in place for a significant period of time, and they are likely to continue to adversely affect our business and results of operations.

In addition, we expect sales cycles, particularly for new customers, to continue to be impacted as a result of the COVID-19 pandemic, and we have observed continued volatility in YUPELRI sales. Sales momentum has been affected by COVID-19 and may continue to be in the future. We market YUPELRI in the hospital setting, where healthcare workers are prioritizing the treatment of patients with or suspected of COVID-19 disease. In mid-March 2020, we suspended in-person sales calls to accounts in response to the COVID-19 pandemic. We are currently re-engaging with these customers in-person when certain criteria are met and remotely via telephone calls, electronic mail, digital outreach or video conferencing as we seek to continue to support healthcare professionals and patient care. Customer orders or new patient use of YUPELRI may decline as a result of, among other things, a shift in our marketing efforts to remote communication methods, increased workload of healthcare providers, and the impact of the Center for Disease Control interim guidelines for limiting the exposure of health care workers to the virus that causes COVID-19, in which drug nebulization in COVID-19 positive patients is listed as a high-risk procedure while present in the room for procedures when the healthcare providers' eyes, nose, or mouth are not protected. We are preparing for continued volatility during 2021 as disruptions of day-to-day operations of hospitals and clinics may continue. In addition, while we do not currently anticipate any supply issues, the COVID-19 pandemic could impact our supply of YUPELRI in the future. At this stage, we are unable to predict with certainty the ultimate disruptive impact of the COVID-19 pandemic on both YUPELRI and the rest of our business.

In addition, the COVID-19 pandemic makes the conduct of clinical trials more challenging given the paramount importance of adequate safety monitoring, collection of data and distribution of study drug, all of which are traditionally achieved by in-person visits to our study sites. We expect challenges to continue to arise from quarantines, shelter-in-place or stay-at-home orders, site closures, travel limitations, potential interruptions to the supply chain for investigational products, other measure to help prevent the spread of COVID-19 or other considerations if site personnel or trial participants become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures. In light of the COVID-19 pandemic, the Company is implementing mitigation plans to help ensure patients in the clinical trials have continued access to drug supply and regular visits with their physicians for study visits per trial protocols, but there is a risk that our trial data could be impacted if our efforts are insufficient. It is also possible that demand for products that we may pursue could be materially and adversely affected as a result of COVID-19 and any related economic impact. Furthermore, we cannot assure you that our publicly-announced initiatives addressing COVID-19 will result in commercially-viable products.

The spread of COVID-19 has caused us to modify our business practices (including employee travel, mandating that all personnel other than key operations and lab personnel work from home, temporary closures of offices, and reduction of physical participation in commercial activities, meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. There is no certainty that such actions will be sufficient to mitigate the risks posed by the virus or otherwise be satisfactory to government authorities. If significant portions of our workforce, and particularly our field-based teams and laboratory staff, are unable to work effectively, including due to illness, quarantines, social distancing, government actions or other restrictions in connection with the COVID-19 pandemic, our operations will be impacted. The COVID-19 pandemic could limit the ability of our customers, suppliers and business partners to perform under their contracts with us, including third-party payers' ability to make timely payments to us during and following the pandemic. We may also experience a shortage of supplies and materials or a suspension of services from third parties. Additionally, while the potential economic impact brought by, and the duration of, the coronavirus pandemic is difficult to assess or predict, the impact of the coronavirus on the global financial markets may reduce our ability to access capital, which could negatively impact our long-term liquidity. Even after the COVID-19 pandemic subsides, we may continue to experience an adverse impact to our business as a result of its global economic impact, including any recession that has occurred or may occur in the future.

The extent to which the COVID-19 pandemic impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and difficult to predict, including, but not limited to, the duration and spread of the pandemic, its severity, the actions to contain the virus or address its impact, vaccine rollout and how quickly and to what extent normal economic and operating activities can resume. There are no comparable recent events which may provide guidance as to the effect of the spread of the COVID-19 pandemic, and, as a result, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects are likely to continue to have a material adverse impact on our future results of 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 (or perceived adverse developments or results) 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 or partner decisions not to maintain a partnership with us;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- 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 or suspensions of the conduct of the clinical trials and changes in regulatory requirements, policy and guidelines, including as a result of any class-based risks that emerge as an area of FDA or other regulatory agency focus;
- challenges related to the COVID-19 pandemic, including with recruitment and/or progressing patients through studies;
- failure of our partners to advance our product candidates through clinical development;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a 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 as we are currently experiencing due to the COVID-19 pandemic, any halting of development in our programs, any difficulties or delays encountered with regard to the FDA or other third country 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.

In July 2019, the FDA issued a Boxed Warning for a systemically active pan-JAK inhibitor, calling out an increased risk of pulmonary embolism and death following the results of a safety study in patients with rheumatoid arthritis. We are focused on developing pan-JAK inhibitors that are designed to remain organ-selective so that they do not become systemically active in order to minimize the risk of side effects. It is unknown at this time what, if any, additional requirements the FDA may put in place with respect to the development of JAK inhibitors generally or what other future FDA actions may have on the prospects for JAK inhibitors. Delays or adverse developments or results or perceived adverse developments or results relating to JAK inhibitors could harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that additional non-clinical or clinical studies are required with respect to our JAK inhibitor programs;
- safety, efficacy or other concerns relating to our JAK inhibitor programs or JAK inhibitors under development or commercialized by other companies;
- the FDA determining that class-based warnings are required for JAK inhibitors generally; or

- any change in FDA policy or guidance regarding JAK inhibitors.

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 comply with the regulatory requirements for the quality of medicinal products and 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 non-clinical 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. See the risk factor entitled "*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*" above for additional information. The rapidly shifting environment surrounding the collective response to the COVID-19 pandemic has led to additional guidance from US and foreign regulatory agencies with respect to numerous matters regarding the conduct of clinical trials in general and the development of COVID-19 related therapies, which is subject to the risk of further change, misinterpretation or non-compliance due to the rapidly changing regulatory landscape. 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 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 existing 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 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 izencitinib in 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 any 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 YUPELRI, including potential post-marketing clinical studies;
- 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 any approved products 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 to meet our capital needs or to take advantage of opportunistic market conditions. 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 preclinical 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 debt secured by some or all of our assets, 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. Neither the terms of our $230.0 million of 3.25% convertible senior notes, due 2023 (the "Convertible Senior 2023 Notes") nor the terms of the Issuer II's 9.5% Fixed Rate Term Notes due on or before 2035 (the "Non-Recourse 2035 Notes") restrict our ability to issue additional debt. If additional debt is issued or we otherwise borrow additional funds, 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. Moreover, 75% of the income from our investment in TRC, as evidenced by the Issuer II Class C Units, is currently available only for payment of the Non-Recourse 2035 Notes and is not available to pay our other obligations or the claims of our other creditors. 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. 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.

In January 2015, we entered into a collaboration agreement with Viatris for the development and commercialization of a nebulized formulation of our LAMA revefenacin, including YUPELRI. Under the terms of the agreement, we and Viatris will co-develop nebulized revefenacin, including YUPELRI, 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 in development for gastrointestinal motility disorders. Under the terms of the agreement, Takeda is responsible for worldwide development and commercialization of TD-8954. In February 2018, we announced a global co-development and commercialization agreement with Janssen for izencitinib and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease. In December 2019, we entered into a License Agreement with Pfizer Inc. ("Pfizer"). Under the license agreement, we provide Pfizer with an exclusive global license to develop, manufacture and commercialize compounds from our preclinical program for skin-targeted, locally-acting pan-Janus kinase (JAK) inhibitors that can be rapidly metabolized. We also have an exclusive development and commercialization agreement with Alfasigma for velusetrag, our internally discovered 5-HT4 agonist for the treatment of gastromotility disorders, under which we have transferred to Alfasigma global rights for velusetrag. 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.

Our partners have in the past and may in the future not fulfill all of their obligations under these agreements, and, in certain circumstances, they or we may terminate our partnership with them. In addition, our partners may also be facing significant business interruptions as a result of the COVID-19 pandemic. 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. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. 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 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") (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters), which agreements govern Innoviva's and GSK's respective interests in the GSK-Partnered Respiratory Programs. Our equity interest primarily covers TRELEGY (the combination of fluticasone furoate, umeclidinium, and vilanterol in a single ELLIPTA inhaler) products. 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 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. We have had, currently have and may in the future have disagreements with Innoviva and TRC regarding Innoviva's decisions regarding the management of TRC that could require invoking the dispute resolution procedures set forth in the TRC LLC Agreement and that, if resolved in a manner adverse to our interests, could have a material impact on our operations. See *Part II, Item 1 "Legal Proceedings."* 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, including any adverse impacts on GSK's operations as a result of the COVID-19 pandemic.

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, our business will be harmed, and the price of our securities could fall.

We have no access to non-public information regarding the development progress of, or plans for, the GSK-Partnered Respiratory Programs, including TRELEGY, and we have little, if any, ability to influence the progress of those programs because our interest in these programs is only through our ownership 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 required quality, 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:

- disappointing or lower than expected sales of TRELEGY;
- the emergence of new closed triple or other alternative therapies or any developments regarding competitive therapies, including comparative price or efficacy of competitive therapies;

- disputes between GSK and Innoviva or between us and Innoviva, such as our 2019 arbitration and our current dispute with Innoviva (See *Part II, Item 1 "Legal Proceedings"*), each of which concern the withholding of royalty payments we believe are due to us under the TRC LLC Agreement;
- GSK deciding to modify, delay or halt the TRELEGY program;
- the FDA and/or other national or foreign regulatory authorities determining that any of the studies under the TRELEGY program does not demonstrate the required quality, safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the program;
- any adverse effects resulting from the COVID-19 pandemic;
- any safety, efficacy or other concerns regarding the TRELEGY program or any GSK-Partnered Respiratory Program in which we have a substantial economic interest; or
- any particular FDA requirements or changes in FDA policy or guidance regarding the TRELEGY program or any other GSK-Partnered Respiratory Program or any particular regulatory requirements in other jurisdictions or changes in the policies or guidance adopted by foreign regulatory authorities.

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 December 31, 2020, GSK beneficially owned 15.0% of our outstanding ordinary shares (although GSK, through a subsidiary, has issued $280,336,000 of exchangeable senior notes due 2023 (the "GSK Notes"), initially exchangeable into 9,644,792 of our ordinary shares which, as of December 31, 2020, represented 15.0% 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. For example, GSK's commercialization efforts are 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, which include TRELEGY. 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. 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 or between us and either of 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. Other examples of these kinds of issues include but are not limited to non-performance of other 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 respiratory programs partnered with GSK, the enforceability of the GSK Agreements or the relationship/partnership between Innoviva and GSK or between us and Innoviva could result in significant reduction in the market price of our securities and other material harm to our business.

We do not control the commercialization of TRELEGY and we do not control TRC; accordingly the amount of royalties we receive will depend on, among other factors, GSK's ability to further commercialize TRELEGY and TRC's decisions concerning use of cash in accordance with the TRC LLC Agreement.

We only receive revenues from TRELEGY based on the amount of sales of this product by GSK in the form of our economic interest in the royalties paid by GSK to TRC, which is managed by Innoviva. There are no required minimum future payments associated with the product and any royalties we receive will depend on GSK's ability to commercialize the product, the future payments, if any, made by GSK to TRC, TRC's expenses, and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement. Following our 2019 arbitration with Innoviva concerning its withholding of certain royalty distributions to the TRC members, the arbitrator ruled, among other things, that in the future if Innoviva desires to invest TRC funds in any initiatives that require the consent of GSK under the collaboration agreement, Innoviva must first obtain the consent of GSK. The timeframe for seeking GSK's consent for these initiatives and the associated dates by which GSK's consent must be received means that royalty distributions could be delayed for several quarters (if GSK ultimately does not consent) or perhaps not made at all until the completion of the initiatives (to the extent that GSK does consent and agrees with TRC that TRC funding will be used for such initiatives). This involves a number of risks and uncertainties, including:

- any future withholding by Innoviva or TRC of royalty distributions;
- GSK's ability to have an adequate supply of TRELEGY product;
- ongoing compliance by GSK or its suppliers with the FDA's current Good Manufacturing Practice;
- compliance with other applicable FDA and other regulatory requirements in the US or other foreign jurisdictions, including those described elsewhere in this report;
- competition, whether from current competitors or new products developed by others in the future;
- claims relating to intellectual property;
- any future disruptions in GSK's business which would affect its ability to commercialize TRELEGY, including, disruptions due to the COVID-19 pandemic;
- the ability of TRELEGY to achieve wider acceptance among physicians, patients, third-party payors, or the medical community in general;
- the amount of cash associated with any additional future TRELEGY commercialization initiatives that Innoviva proposes to GSK for TRC to pursue, the time it may take to present those initiatives to GSK for approval and the time it takes for GSK to consent or not consent;
- global economic conditions;
- decisions made by Innoviva, as TRC's manager, regarding the timing and amount of distributions;
- the resolution of any disputes between Innoviva and TRC, on the one hand, and us, on the other, regarding the timing of distributions, the amount of distributions, and the proper business activities of TRC, including the current dispute with Innoviva and TRC described below; and
- any of the other risks relating to commercialization of TRELEGY.

These risks and uncertainties could materially impact the amount and timing of future royalties or other revenues we may receive from sales of TRELEGY, which could have a material adverse effect on our future revenues, other financial results and our financial position and cause the price of our securities to fall.

On June 10, 2020, we disclosed in a Form 8-K that we had formally objected to TRC and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to us under the terms of the TRC LLC Agreement. We intend to

continue to seek to protect our interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, we initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to us in a manner consistent with the TRC LLC Agreement and our 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the first quarter or early in the second quarter of 2021. There can be no assurance that we will prevail in the arbitration or that it will result in us receiving additional distributions from TRC. An adverse result could materially and adversely affect the funds that we and our affiliates would otherwise expect to receive from TRC in the future.

In the future, Innoviva may cause TRC to withhold funds from distribution to its members, including our affiliates, for additional TRELEGY development or commercialization initiatives that may be proposed, which would need to be approved by GSK in order to be implemented, or for other purposes. To the extent any TRELEGY development or commercialization initiatives are timely approved by GSK and implemented, such initiatives may require funding beyond the amount withheld by TRC, and TRC may withhold additional amounts in subsequent quarters with respect to these initiatives. Accordingly, we cannot predict the amount of the funds that our affiliates would otherwise expect to receive from TRC that TRC may withhold in the future, or the timing of any such withholding.

We may object to the withholding of funds for additional proposed TRELEGY initiatives or other purposes on the basis that such withholding is in violation of the terms of the TRC LLC Agreement or otherwise, and such objection could result in additional legal proceedings between us, TRC and Innoviva. Any such legal proceedings could divert the attention of management and cause us to incur significant costs, regardless of the outcome, which we cannot predict. An adverse result could materially and adversely affect the funds that our affiliates would otherwise expect to receive from TRC in the future and thus have a material adverse effect on our business, financial condition, and results of operations.

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 clinical studies for our current product candidates, such as the clinical studies for our JAK inhibitor programs or ampreloxetine in patients with nOH, are substantially delayed or suggest that any of our product candidates 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 US 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. For example, YUPELRI competes predominantly with the nebulized LAMA Lonhala® Magnair® (glycopyrrolate) dosed two times per day and with short acting nebulized bronchodilators that are dosed three to four times 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 izencitinib and related back-up compounds for inflammatory intestinal diseases, including ulcerative colitis and Crohn's disease and Viatris for the development and commercialization of a nebulized formulation of revefenacin, our LAMA compound (including YUPELRI). 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 and to commercialize the product candidates in our programs if approved by the necessary regulatory authorities. 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. In addition, effective collaboration with a partner requires coordination to achieve complex and detail-intensive goals between entities that potentially have different priorities, capabilities and processes and successful navigation of the challenges such coordination entails. For example, Viatris has a substantial existing product portfolio and other considerations that influence its resource allocation, and other priorities and internal organizational processes that differ from our own. As a result of these differing interests and processes, Viatris 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. 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 non-clinical and 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 (“GXPs”) 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. Furthermore, to the extent the operations of these third parties are disrupted as result of the COVID-19 pandemic or otherwise, our development programs could be delayed.

The FDA, and equivalent authorities in third 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 US), 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.

There is a single source of supply for a number of our product candidates and for YUPELRI, 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. In addition, there is a single supplier of YUPELRI API and a single supplier of YUPELRI drug product. If, for any reason, any of these third-party manufacturers are unable or unwilling to perform, or if their performance does not meet regulatory requirements, alternative manufacturers may not be available or may not be available on acceptable terms. 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, prevent us from developing our product candidates in a cost-effective manner or on a timely basis or adversely impact the commercialization of YUPELRI. 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.

We have a significant amount of debt, including our Non-Recourse 2035 Notes and Convertible Senior 2023 Notes, that are senior in capital structure and cash flow, respectively, to holders of our ordinary shares. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our shareholders.

As of December 31, 2020, we had $649.2 million in total long-term liabilities outstanding, comprised primarily of $378.3 million in net principal that remains outstanding under the Issuer II's (defined below) Non-Recourse 2035 Notes and $230.0 million in principal that remains outstanding under our Convertible Senior 2023 Notes (together with the Non-Recourse 2035 Notes, the "Notes").

The Convertible Senior 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date except for certain changes in tax law. Holders of the Convertible Senior 2023 Notes may require us to purchase all or any portion of their notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change such as a change of control of us or the termination of trading of our ordinary shares in accordance with the indenture governing the Convertible Senior 2023 Notes.

Until the Non-Recourse 2035 Notes are paid in full, holders of the Non-Recourse 2035 Notes have a perfected security interest in the Issuer II Class C Units that represent a 63.75% economic interest in any future payments that may be made by GSK to TRC under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, including the TRELEGY program.

Prior to and including the December 5, 2024 payment date, the terms of the Non-Recourse 2035 Notes provide that in the event that the distributions received by the Issuer II from TRC in a quarter is less than the interest accrued for that quarter, the principal amount of the Non-Recourse 2035 Notes will increase by the interest shortfall amount for that quarter. The terms of the Non-Recourse 2035 Notes also provide that Theravance Biopharma, at its option, may satisfy the quarterly interest payment obligations by making a capital contribution to the Issuer II.

Satisfying the obligations of these Notes could adversely affect the amount or timing of any distributions to our shareholders. In addition, the Non-Recourse 2035 Notes may be redeemed by Issuer II on and after February 28, 2022, in whole or in part, at specified redemption premiums. We may further choose to satisfy, repurchase, or refinance any Non-Recourse 2035 Notes, to the extent allowable, through public or private equity or debt financings if we deem such financings are available on favorable terms. If any or all of the Convertible Senior 2023 Notes are not converted into our ordinary shares before the maturity date, we will have to pay the holders the full aggregate principal amount of the Convertible Senior 2023 Notes then outstanding. If the Non-Recourse 2035 Notes are not refinanced or paid in full the holders of the Non-Recourse 2035 Notes will have the right to foreclose on the Issuer II Class C Units that represent a 63.75% economic interest in future royalties due on net sales of TRELEGY and related assets. If the Issuer II Class C Units are foreclosed upon, we will lose any right to receive 75% of the future royalty payments made by GSK in connection with the net sales of TRELEGY and related assets. Any of the above payments could have a material adverse effect on our cash position. Our failure to satisfy these obligations may result in a default under the applicable indenture governing these Notes, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall. For more information, see Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources**.**

Servicing our Convertible Senior 2023 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 Convertible Senior 2023 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 Convertible Senior 2023 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 Convertible Senior 2023 Notes and any future indebtedness we may incur and to make necessary capital expenditures. In addition, the issuance of the Non-Recourse 2035 Notes reduced the cash available for us to make interest or principal payments on, or to refinance, the Convertible Senior 2023 Notes. 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 Convertible Senior 2023 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 Convertible Senior 2023 Notes or future indebtedness.

The holders of the Convertible Senior 2023 Notes may have the right to require us to repurchase the Convertible Senior 2023 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 governing the Convertible Senior 2023 Notes. We may not have sufficient funds to repurchase the Convertible Senior 2023 Notes in cash or have the ability to arrange necessary financing on acceptable terms. Our failure to repurchase the Convertible Senior 2023 Notes when required would result in an event of default with respect to the Convertible Senior 2023 Notes. In addition, any acceleration of the repayment of the Convertible Senior 2023 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. As another example, we may incur penalties imposed by the competent authorities in the EU Member States in case of breach of the EU rules governing the collection and processing of personal data, including unauthorized access to or disclosure of personal 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 (which has since been resolved) against a former employee for misappropriation of 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. These same risks also apply to our partners and vendors, who similarly hold sensitive and critical information related to our business in computer systems and are similarly potentially vulnerable to attack.

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 our products, if any, 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 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 United Kingdom ("UK") recent withdrawal from the EU (often referred to as "Brexit"), current global economic challenges, the COVID-19 pandemic, and other disruptions to global and regional economies and markets.

Brexit has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate in the event of a withdrawal. From a regulatory perspective, the UK's withdrawal bears significant complexity and risks.

In light of the fact that a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit could materially impact the EU regulatory regime governing development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, a marketing authorization for a

medicinal product granted by the European Commission or by the competent authorities of EU member states will no longer encompass the UK. A separate authorization granted by the UK competent authorities will be required to place medicinal products on the UK market. In addition, the UK's withdrawal from the EU affects manufacturing sites that hold an EU manufacturing authorization issued by the UK competent authorities which could impact our ability to rely on UK manufacturing sites to supply medicinal products intended for the EU market will depend on. All of these changes could increase our costs and otherwise adversely affect our business. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and to the US dollar have already been, and may continue to be, negatively affected by Brexit, which could cause volatility in our quarterly financial results.

Further, development of our product candidates and/or regulatory approval may be delayed for other political events beyond our control. For example, a US federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018, and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 similar events 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.

If YUPELRI does not continue to be accepted by physicians, patients, third-party payors, or the medical community in general, we may not receive significant additional revenues from sales of this product.

The commercial success of YUPELRI depends upon its acceptance by physicians, patients, third-party payors and the medical community in general. YUPELRI may not continue to be accepted by these parties. YUPELRI competes predominantly with the nebulized LAMA Lonhala® Magnair® (glycopyrrolate) dosed two times per day and with short acting nebulized bronchodilators that are dosed three to four times per day. We have seen increased volatility in sales of YUPELRI coinciding with the suspension of in-person sales calls, having less access to physicians and other healthcare providers and the progression of the COVID-19 pandemic and, if physicians, patients, third-party payors, or the medical community in general believe that nebulized therapy presents a risk of further spreading COVID-19 or that YUPELRI is otherwise not a preferred treatment option for those with COPD, we may see long-term declines. Shifts to novel marketing tactics are being deployed in an effort to keep awareness levels and business generation positive, but these untested and unvalidated tactics may not be effective at maintaining YUPELRI brand growth. If YUPELRI's acceptance does not continue to grow, or declines from previous levels, our business and financial results could be materially harmed.

In collaboration with Viatris, we are responsible for marketing and sales of YUPELRI in the US, which subjects us to certain risks.

We currently maintain a sales force in the US and plan to continue to augment our sales and marketing personnel to support our co-promotion obligations for YUPELRI under our agreement with Viatris. The risks of fulfilling our US co-promotion obligations to Viatris include:

- costs and expenses associated with maintaining an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure, 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 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 YUPELRI, 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 a sales and marketing organization with appropriate experience, technical expertise, supporting infrastructure and the ability to obtain access to and educate adequate numbers of physicians about prescribing YUPELRI in appropriate clinical situations, we will have difficulty maintaining effective commercialization of YUPELRI in the hospital setting, which would adversely affect our business and financial results and the condition and the price of our securities could fall.

We are subject to extensive and ongoing regulation, oversight and other requirements by the FDA 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 any approved products.

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 an approved product, such as YUPELRI, that are outside the scope of those uses that have been expressly approved by the FDA as safe and effective on the product's label.

The manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for an 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 any approved product, such as YUPELRI, as well as governmental authorities in those foreign countries in which any product is 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 materially limit the ability to commercialize a product or any future product candidates and if we fail to comply with FDA regulations and requirements, 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 the product into interstate commerce in the US, 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 those commercializing products with respect to which we have an economic interest or right to receive royalties, including GSK and Cumberland Pharmaceuticals Inc. ("Cumberland"), and such regulatory actions and oversight may limit those parties' 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 and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties may face competition from companies seeking to market generic versions of any approved products in which we have an interest, such as TRELEGY or YUPELRI.

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 YUPELRI until at least 2025 that are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, and those commercializing products with respect to which we have an economic interest or right to receive royalties similarly have patents protecting their products, such as TRELEGY and VIBATIV, 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 nor are we aware of any with respect to products in which we have an economic interest or right to receive royalties, but if any competitors successfully challenge the patents related to these products, we and/or our collaboration partners and those commercializing products with respect to which we have an economic interest or right to receive royalties 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 YUPELRI, 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 US, the UK 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 has implemented certain tax law changes and is expected to implement additional tax law changes to comply with the European Union Anti-Tax Avoidance Directives. These changes include the first ever Irish controlled foreign company ("CFC") rules which came into effect on January 1, 2019. Due to provisions in *Finance Bill 2019*, Ireland will also implement certain transfer pricing rule changes, with effect from 2020. We are continuing to evaluate and monitor the applicability of the CFC rules published in *Finance Act 2018*, but our current assessment, based on the rules and guidance published to date, is that the rules are unlikely to have a material impact on our operations. Statutory language has been provided for the transfer pricing rule changes, and we believe that the transfer pricing rules are unlikely to have a material impact on our operations. New UK tax legislation was introduced by the *Finance Act 2019* ("FA 2019") that imposes a tax related to offshore receipts in respect of intangible property held in low tax jurisdictions ("ORIP") and became effective in April 2019. FA 2019 also included a power for amendments to the ORIP legislation to be made by regulation by December 31, 2019. On October 15, 2019, the UK published further guidance intended to facilitate the administration of the ORIP regime. However, a number of issues and areas of uncertainty remain. We have reviewed the original legislation in conjunction with the guidance and believe that the ORIP regime may apply to certain cash receipts. Based on this analysis, we believe that the ORIP charge on UK-derived cash receipts through 2020 is not material.

In April 2020, we became aware of a withholding tax regulation that could be interpreted to apply to certain of our previous intra-group transactions. Additional draft guidance on this withholding tax regime was released in late 2020 and early 2021, and based on our analysis of this guidance, we do not believe the exposure to be material. We continue to monitor the evolving legislation relating to this matter and will consider its impact on our consolidated financial statements.

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 2020, 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 2020, we do not believe that our Company is a PFIC since 2015. Based on existing tax law, 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 Ireland Limited. 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 US. 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 (i) 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 (ii) the TRC LLC 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 LLC Agreement and any changes to the governance structure of TRC, the confidentiality restrictions, the consent rights, and the transfer restrictions in the TRC LLC 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 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 certain of our directors and officers 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 Cumberland, or if we are not able to enforce our indemnification rights against Innoviva or Cumberland, 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 enforce our indemnification rights against Innoviva, our business prospects and financial condition may be harmed.

In addition, the agreement relating to the sale of VIBATIV to Cumberland contains indemnification obligations of both us and Cumberland. If we are required to indemnify Cumberland or if we are unable to enforce our indemnification rights against Cumberland for any reason, our business 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 December 31, 2020, we owned 507 issued US patents and 2,253 granted foreign patents, as well as additional pending US 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 US. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the US 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 for misappropriation of certain of our confidential, proprietary and trade secret information. While this litigation has since been resolved, 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 is successfully challenged or encounters problems with the US 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. 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. In California, the California Consumer Privacy Act ("CCPA") took effect on January 1, 2020. The CCPA establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in areas affecting our business. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with the such laws. Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, 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, and its implementing regulations, (collectively, "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, use, 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 General Data Protection Regulation ("GDPR") which became applicable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. These obligations and restrictions concern, in particular, the consent of the individuals to whom the personal data relate, the information provided to the individuals, the transfer of personal data out of the European Economic Area ("EEA") or Switzerland, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be 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 service 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, particularly the GDPR which imposes specific and relevant obligations.

Legal mechanisms to allow for the transfer of personal data from the EEA to the US have been challenged in the European Court of Justice, which generally increases uncertainty around compliance with EU privacy law requirements as these relate to transfer of data from the EU to the US. In 2016, the European Commission and the US Department of Commerce ("DOC") put in place the EU US "Privacy Shield," which has been relied on by some US companies since that time to transfer data to the US, and, in its third annual review of the Privacy Shield in October 2019, the European Commission concluded that the US continues to ensure an adequate level of protection for personal data transferred under the Privacy Shield. However, on July 16, 2020, the European Court of Justice ruled that the Privacy Shield is invalid. As a result, from July 16, 2020 companies may no longer rely on the Privacy Shield as a basis on which to transfer personal data from the EU to the US. US-based companies are permitted to rely on other authorized means and procedures to transfer personal data provided by the GDPR. However, the most common authorized procedure to transfer personal data out of the EU, the European Commission's Standard Contractual Clauses, may, as a result of the Court judgement of July 16, 2020, also come under increased scrutiny. Following the Court's ruling, the European Data Protection Board issued a statement providing among other things that it is a primary responsibility of the exporter and the importer, when considering whether to rely on Standard Contractual Clauses to export data from the EU to third countries, to ensure that these third countries maintain a level of protection that is essentially equivalent to that guaranteed by the GDPR in light of the EU Charter of Human Rights. Companies may need to revise their Standard Contractual Clauses in light of the July 16, 2020 judgement. Companies that have not taken steps to demonstrate that their Standard Contractual Clauses and personal data recipients in the US are suitable to transfer to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules.

In addition, the privacy and data security landscape in the EU continues to remain in flux. The agreement that has been concluded between the EU and the UK following the UK's withdrawal from the EU on January 31, 2020 may require organizations to revisit the way they transfer personal data from and to the UK from the EU. The Trade and Cooperation Agreement concluded between the EU and the UK provides for a transition period of six months starting January 1, 2021. During this period personal data may, in accordance with the requirements of the GDPR, flow from the EEA to the UK and from the UK to the EEA. If the European Commission does not adopt an Adequacy Decision concerning the level of data protection in the UK within this six month period, any potential flows of personal data between the EEA and the UK will subsequently be subject to the same restrictions as those imposed on other third countries.

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, including an order to stop transferring the personal data outside of the EEA and significant penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA or Switzerland to the US is restricted, which could adversely impact our operating results.

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 us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties.

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 us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties in regard to one or more of the following:

- the ability to set and collect a price believed to be reasonable for products;
- the ability to generate revenues and achieve profitability; and
- the availability of capital.

The pricing and reimbursement environment for 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 US 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 US, the pharmaceutical industry has been a particular focus of these efforts and has been and may in the future be significantly affected by major regulatory or legislative initiatives. For instance, while Medicare Part B payment for most drugs has been established at the average sales price of the drug plus 6% (reduced to 4.3% as a result of sequestration), a regulatory change may alter the level of payment for some drugs. In a November 20, 2020 interim final rule, Center for Medicare and Medical Services ("CMS") established a "Most Favored Nation" demonstration model that would lower Medicare Part B reimbursement of certain drugs based on international reference prices. The rule has become subject to judicial challenges, and federal courts have enjoined the rule at this time. There is also proposed legislation pending that would establish an international reference price-based payment methodology. We expect we, our collaboration partners or those commercializing products with respect to which we have an economic interest or right to receive royalties may experience pricing pressures in connection with the sale of drug products, 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 US, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges, and expansion of the Medicaid program. This law has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted 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 Act's 340B drug pricing program, fraud and abuse and enforcement. These changes have impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

In particular, 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. 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. On December 21, 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); provide definitions for "line extension," "new formulation," and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022); and revise best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, specifically regarding applicability of such exclusions in the context of pharmacy benefit manager "accumulator" programs (beginning in 2023). It is currently unclear whether the Biden administration will delay or suspend implementation of this final rule. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program has increased and will continue to increase the costs and the complexity of compliance, has been and will be time-consuming to implement, and could have a material adverse effect on results of operations for us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, particularly if CMS challenges the approach we take in our implementation of the final regulation.

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 the sales, business and financial condition of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties. 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.

Certain provisions of the Healthcare Reform Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 (the "Tax Act"), 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, effective January 1, 2019. Currently, the Supreme Court is considering whether the Healthcare Reform Act's individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the Healthcare Reform Act are inseverable from the mandate. A ruling is expected by mid-2021 and could produce any of a number of results, including invalidation of the Healthcare Reform Act in its entirety if there is a finding of inseverability. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace, or invalidate the Healthcare Reform Act or its implementing regulations, or portions thereof, will affect the Healthcare Reform Act or our business. Additional legislative changes to and regulatory changes under the Healthcare 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, its implementation, efforts to repeal or replace, or invalidate the Healthcare Reform Act, or portions thereof, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on the ability of us, our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties to maintain or increase sales of existing products or to successfully commercialize product candidates, if approved.

The Bipartisan Budget Act of 2018, among other things, amended the Healthcare Reform Act to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Additionally, in November 2020, the U.S. Department of Health and Human Services finalized a previously abandoned proposal to amend the discount safe harbor regulation of the federal anti-kickback statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-of-pocket costs. The rule, which takes full effect January 1, 2022, revises the discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through pharmacy benefit managers (PBMs), creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at the point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. It is too early to know what the effect of the rule will be on negotiations of coverage for our products with Medicare Part D plans, or whether the rule will affect our coverage arrangements with commercial insurers. It is also unclear whether the rule will have the intended effect of reducing net prices and beneficiary out-of-pocket costs without also increasing Medicare Part D premiums, which may impact the willingness of Part D plans to cover our products and the price concessions or other terms the plans or their PBMs may seek from us. There have been other proposals to modify the Medicare Part D benefit, including by imposing 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 including any that result in additional rebates, this could have a negative impact on revenues for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

On August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2021) unless Congress takes additional action. As long as these cuts remain in effect, they could adversely impact payment for any products that are reimbursed under Medicare.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. For example, California has enacted a prescription drug price transparency

law requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs with prices that exceed a specified threshold, and to report new prescription drugs introduced to the market at a wholesale acquisition cost exceeding the Medicare Part D specialty drug threshold.

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 product or additional pricing pressures for our collaboration partners, or those commercializing products with respect to which we have an economic interest or right to receive royalties, which could impact our revenues.

If we failed 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.

Prior to the sale of VIBATIV to Cumberland, we had certain price reporting obligations to the Medicaid Drug Rebate program and other governmental pricing programs, and we had obligations to report average sales price under the Medicare program. Following the consummation of the transaction with Cumberland, our price reporting obligations related to VIBATIV have been transitioned to Cumberland, and price reporting obligations for YUPELRI reside with Viatris. However, we retain liability related to price reporting for VIBATIV for historic periods.

Under the Medicaid Drug Rebate program, a manufacturer is required to pay a rebate to each state Medicaid program for its 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 the manufacturer 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.

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. Manufacturers also are required to report their 340B ceiling prices to HRSA on a quarterly basis, and HRSA then publishes them to 340B covered entities. A final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability.

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.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by the manufacturer, governmental or regulatory agencies and the courts. A manufacturer that becomes aware that its Medicaid reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, is obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase the 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 340B ceiling price.

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 significant civil monetary penalties 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 significant civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied. If we are found to have charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties. Our failure to submit the required price data on a timely basis could result in a significant civil monetary penalty 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.

In order to be eligible to have its 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, a manufacturer is 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, the manufacturer is obligated to make its covered drugs 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 the manufacturer calculates and reports 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 significant penalties 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, the manufacturer is required to pay quarterly rebates to DoD on utilization of its 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. A manufacturer that overcharges the government in connection with the FSS contract or Tricare Retail Pharmacy Rebate Program, whether due to a misstated FCP or otherwise, is 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.

Individual states in the United States, as noted, have also passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including marketing cost disclosure and transparency measures. Some states require the submission of reports related to pricing information, including based on the introduction of new prescription drugs, certain increases in wholesale acquisition cost of prescription drugs, marketing of prescription drugs within the state, and sales of prescription drugs in or into the state. Some states may pursue available enforcement measures, including imposition of civil monetary penalties, for a manufacturer's failure to report such information.

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 US 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 or product assistance programs.

- The federal civil False Claims Act prohibits, 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. Private individuals, commonly known as "whistleblowers," can bring civil False Claims Act *qui tam* actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. 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 companies' 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 significant mandatory penalties per false claim or statement for violations. 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 penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- HIPAA, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors, 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. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. 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.

- 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 any third-party payors, including private insurers or patients. 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 require the posting of information relating to clinical studies and their outcomes. 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, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the US and similar programs outside the US, contractual damages, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. 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.

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 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. In addition, as a result of the exchangeable note offering by GSK, up to 9,644,792 ordinary shares held by GSK could become freely tradeable after September 1, 2020, if holders of the GSK Notes were to exchange their notes for our ordinary shares.

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 YUPELRI, including without limitation, lower than expected sales of YUPELRI, difficulties or delays encountered with regard to the FDA or other regulatory authorities in this program or any indication from clinical or non-clinical studies that YUPELRI is 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, lower than expected sales of TRELEGY, 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 our key clinical development programs, for example our JAK inhibitor program or ampreloxetine, 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 (including any class-based risks that emerge as a FDA or other regulatory agency focus), or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;

- 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 disagreements or perceived adverse developments or disagreements with respect to our relationship with Innoviva, such as our 2019 arbitration proceeding with them or our current arbitration proceeding with them concerning their proposed use of TRC funds to make investments in private companies, or the relationship of Innoviva or TRC on the one hand and GSK on the other hand, including any such developments or disagreements resulting from or relating to the TRC LLC Agreement or 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 US 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 the COVID-19 pandemic and 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, which may be more likely to occur due to the concentration of ownership of our shares, such as what we experienced when our largest shareholder, Woodford Investment Management Limited, divested its holdings in 2019 or which may occur as a result of the exchangeable note offering by GSK if holders of the GSK Notes were to exchange their notes for our ordinary 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 product candidates or medicines 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 December 31, 2020, our three largest shareholders collectively owned 43.5% of our outstanding ordinary shares. These shareholders 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 and other 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.

In addition, in May 2018, our shareholders approved a resolution authorizing our board of directors to adopt a shareholder rights plan in the future intended to deter any person from acquiring more than 19.9% of our outstanding ordinary shares without the approval of our board of directors.

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 (2020 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 US. 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 US or any state of the US.

We understand that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the US predicated upon the civil liability provisions of the securities laws of the US 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 US 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 US, 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.

If securities or industry analysts cease coverage of us or do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and trading volume could decline.

The trading market for our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our ordinary shares could be negatively affected. If one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business or if our results fail to meet the expectations of these analysts, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause our share price and trading volume to decline.

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 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our principal physical properties in the US consist of approximately 170,000 square feet of office and laboratory space leased in two buildings in South San Francisco, California. The South San Francisco lease expires in May 2030. Our Irish subsidiary operates from approximately 6,100 square feet of leased office space in Dublin, Ireland, and the lease expires in April 2027. We believe our current space is sufficient for our needs.

ITEM 3. LEGAL PROCEEDINGS

On June 10, 2020, we disclosed in a Form 8-K that we had formally objected to TRC and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to us under the terms of the TRC LLC Agreement. We intend to continue to seek to protect our interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, we initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to us in a manner consistent with the TRC LLC Agreement and our 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the first quarter or early in the second quarter of 2021.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our ordinary shares have traded on The Nasdaq Global Market under the symbol "TBPH" since June 3, 2014. As of February 19, 2021, there were 68 shareholders of record of our ordinary shares. As many of our ordinary shares are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividend Policy

We currently intend to retain any future earnings to finance our research and development efforts. We have never declared or paid cash dividends on our ordinary shares and do not intend to declare or pay cash dividends on our ordinary shares in the foreseeable future.

Equity Compensation Plans

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2020:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Options	3,082,419	$ 25.09	4,345,599
Restricted shares	4,993,918	n/a	n/a
Employee share purchase plan	n/a	n/a	2,361,457
Equity compensation plans approved by security holders	8,076,337	$ 25.09	6,707,056
Options	216,760	$ 17.27	203,261
Equity compensation plans not approved by security holders	216,760	$ 17.27	203,261
Total	8,293,097	$ 24.58	6,910,317

We have three equity compensation plans — our 2013 Equity Incentive Plan (the "2013 EIP"), our 2013 Employee Share Purchase Plan (the "2013 ESPP"), and our 2014 New Employee Equity Incentive Plan (the "2014 NEEIP"). At inception of the plans, we were authorized to issue 5,428,571 ordinary shares under the 2013 EIP and 857,142 ordinary shares under the 2013 ESPP, and 750,000 ordinary shares under the 2014 NEEIP.

The 2013 EIP provides for the issuance of share-based awards, including restricted shares, restricted share units, options, share appreciation rights ("SARs") and other equity-based awards, to our employees, officers, directors and consultants. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2023, the aggregate number of ordinary shares that may be issued under the 2013 EIP shall automatically increase by a number equal to the least of (i) 5% of the total number of ordinary shares outstanding on December 31 of the prior year; (ii) 3,428,571 ordinary shares; or (iii) a number of ordinary shares determined by our board of directors. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of our 2013 EIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Under the 2013 ESPP, our officers and employees may purchase ordinary shares through payroll deductions at a price equal to 85% of the lower of the fair market value of the ordinary share at the beginning of the offering period or at the end of each applicable purchase period. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2033, the aggregate number of ordinary shares that may be issued under the 2013 ESPP shall automatically increase by a number equal to the least of (i) 1% of the total number of ordinary shares outstanding on December 31 of the prior year; (ii) 857,142 ordinary shares; or (iii) a number of ordinary shares determined by our board of directors. The ESPP generally provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period generally composed of four consecutive six-month purchase periods. The purchase periods end on either May 15 or November 15. ESPP contributions are limited to a maximum of 15% of an employee's eligible compensation.

Our 2013 ESPP also includes a feature that provides for the existing offering period to terminate and for participants in that offering period to automatically be enrolled in a new offering period when the fair market value of an ordinary share at the beginning of a subsequent offering period falls below the fair market value of an ordinary share on the first day of such offering period.

The 2014 NEEIP provides for the issuance of share-based awards, including restricted shares, restricted share units, non-qualified options and SARs, to our employees. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of our 2014 NEEIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. We may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

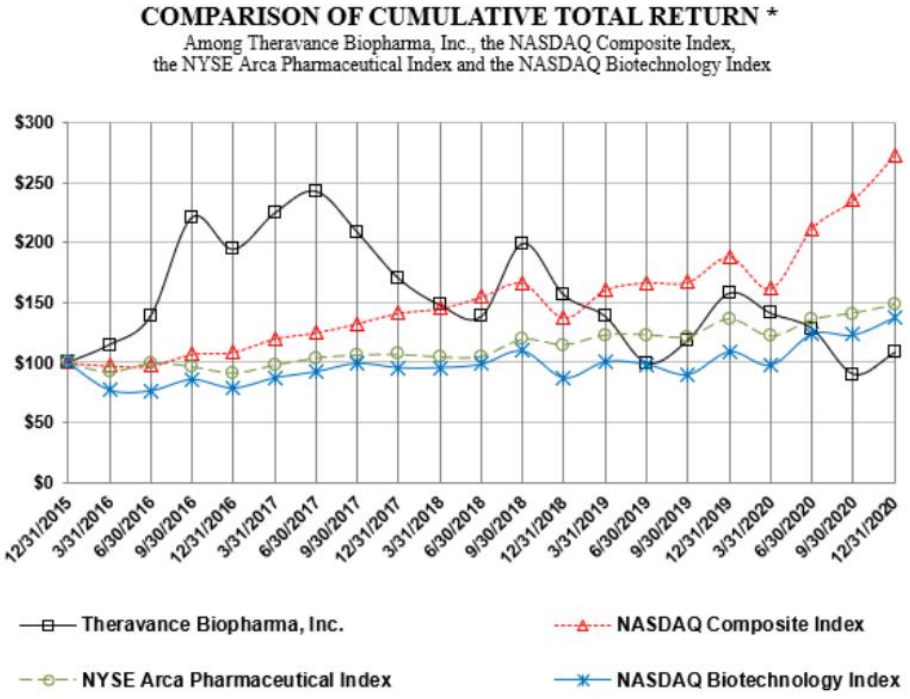
Additional information regarding share-based compensation is included in *"Item 8, Note 1. Organization and Summary of Significant Accounting Policies,"* and *"Item 8, Note 11. Share-Based Compensation,"* to the consolidated financial statements appearing in this Annual Report on Form 10-K.

Share Performance Graph

The graph set forth below compares the cumulative total shareholder return on our ordinary shares from December 31, 2015 through December 31, 2020, with the cumulative total return of (i) the Nasdaq Composite Index, (ii) the NYSE Arca Pharmaceutical Index (previously labeled as the Nasdaq Pharmaceutical Index) and (iii) the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100 on December 31, 2015 in each of (1) our ordinary shares, (2) the Nasdaq Composite Index, (3) the NYSE Arca Pharmaceutical Index and (4) the Nasdaq Biotechnology Index, and assumes the reinvestment of dividends, if any, although dividends have never been declared on our ordinary shares.

The comparisons shown in the graph below are based upon historical data. We caution that the price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our ordinary shares.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act or the Exchange Act that might incorporate this Annual Report on Form 10-K or future filings made by us under those statutes, this Performance Graph section shall not be deemed filed with the SEC and shall not be deemed incorporated by reference into any of those prior filings or into any future filings made by us under those statutes.



* Shows the cumulative return on investment assuming an investment of $100 in our ordinary shares or the indices on December 31, 2015, including the reinvestment of dividends.

$100 Investment in TBPH Shares or Index	TBPH	Nasdaq Composite Index	NYSE Arca Pharmaceutical Index	Nasdaq Biotechnology Index
December 31, 2015	$ 100.00	$ 100.00	$ 100.00	$ 100.00
December 31, 2016	194.51	108.97	91.66	78.65
December 31, 2017	170.16	141.36	106.86	95.67
December 31, 2018	156.13	137.39	114.86	87.19
December 31, 2019	157.96	187.87	135.98	109.08
December 31, 2020	108.42	272.51	147.86	137.90

ITEM 6. SELECTED FINANCIAL DATA

Omitted as permitted under SEC Regulation S-K, Item 301.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis ("MD&A") is intended to facilitate an understanding of our business and results of operations. This discussion and analysis should be read in conjunction with our consolidated financial statements and notes included in this Annual Report on Form 10-K. The information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, our operating expenses, and future payments under our collaboration agreements, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Such statements are based upon current

expectations that involve risks and uncertainties. You should review the section entitled *"Risk Factors"* in Item 1A of Part I above for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See the section entitled *"Special Note regarding Forward-Looking Statements"* above for more information.

Management Overview

Theravance Biopharma is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. Our purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. Our research is focused in the areas of inflammation and immunology.

In pursuit of our purpose, we apply insights and innovation at each stage of our business and utilize our internal capabilities and those of partners around the world. We apply organ-selective expertise to biologically compelling targets to discover and develop medicines designed to treat underserved localized diseases and to limit systemic exposure, in order to maximize patient benefit and minimize risk. These efforts leverage years of experience in developing lung-selective medicines to treat respiratory disease, including the US FDA approved YUPELRI® (revefenacin) inhalation solution indicated for the maintenance treatment of patients with COPD. Our pipeline of internally discovered programs is targeted to address significant patient needs.

We have an economic interest in potential future payments from GSK pursuant to its agreements with Innoviva relating to certain programs, including TRELEGY.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated 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 consolidated 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. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including these estimates, will depend on future developments that are highly uncertain and may be impacted by the emergence of new information concerning the COVID-19 pandemic and the actions taken to contain or treat the disease, including vaccine availability, distribution, acceptance and effectiveness. For more information, see Part I—Item 1—Business—*Impact of COVID-19 Pandemic*. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We recognize revenue under Accounting Standards Codification ("ASC"), Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). 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, an 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.

Collaborative Arrangements under ASC 606

We enter into collaborative arrangements with partners that fall under the scope of Accounting Standards Codification, Topic 808, *Collaborative Arrangements* ("ASC 808"). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of these arrangements. We analogize to ASC 606 for certain activities within collaborative arrangements for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations. Revenue recognized by analogizing to ASC 606 is recorded as "collaboration revenue" or "licensing revenue" whereas, revenue recognized in accordance with ASC 808 is recorded on a separate collaboration revenue line on the consolidated statements of operations.

The terms of our collaborative 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 research and development expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against research and development expense. Where a portion of non-refundable up-front fees or other payments received is allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration 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 our collaborative partner 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.

Up-front Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration 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 collaboration revenue from the allocated transaction price. For example, when we receive up-front fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress each 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 collaborative 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 collaborative 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).

Following the sale of VIBATIV to Cumberland in November 2018, VIBATIV royalties earned from Cumberland are included within "interest and other income, net" on the consolidated statements of operations. In addition, our income earned related to TRELEGY sales is included within "income from our investment in TRC, LLC" on the consolidated statements of operations.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, we have been reimbursed for a portion of our research and development expenses or participate in the cost-sharing of such research and development expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of research and development expense in our consolidated statements of operations, as we do not consider performing research and development services for reimbursement to be a part of our ongoing major or central operations.

Research and Development Expenses

Research and development ("R&D") expenses are recorded in the period that services are rendered or goods are received. R&D expenses consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain R&D activities on our behalf, net of certain external R&D expenses reimbursed under our collaborative arrangements.

As part of the process of preparing our consolidated financial statements, we are required to estimate and accrue certain R&D expenses. This process involves the following:

- identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our consolidated financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to clinical research organizations ("CROs") in connection with preclinical and toxicology studies and clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations ("CMOs") in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers typically invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or

overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, there is no assurance that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities. Such changes in estimates will be recognized as research and development expenses in the period that the change in estimate occurs.

Theravance Respiratory Company, LLC ("TRC")

Through our 85% equity interest in TRC, the Company is 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 (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The primary drug program assigned to TRC is TRELEGY.

We analyzed our ownership, contractual and other interests in TRC to determine if TRC 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 in our consolidated financial statements under the equity method of accounting. Income related to our equity ownership of TRC is reflected within our consolidated statements of operations and is classified as non-operating income.

Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

Our total unrecognized tax benefits of $63.4 million and $58.8 million, as of December 31, 2020 and December 31, 2019, respectively, may reduce the effective tax rate in the period of recognition. We currently have a full valuation allowance against our deferred tax assets, which would impact the timing of the effective tax rate benefit should any of our uncertain positions be favorably settled in the future.

We assess all material positions, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than 50% likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether the factors underlying the sustainability assertion have changed and whether the amount of the recognized tax benefit is still appropriate.

The recognition and measurement of tax benefits requires significant judgment. We have taken certain positions where we believe that our position is greater than 50% likely to be realized upon ultimate settlement and for which no reserve for uncertain tax positions has been recorded. If we do not ultimately realize the expected benefit of these positions, we will record additional income tax expenses in future periods. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Any tax levied or credited by a governmental taxing authority that is not based on our income is outside the scope of accounting for income taxes. Therefore, we record such items as a component in our loss before income taxes.

Results of Operations

The following tables set forth our results of operations for the periods presented. Management's commentary for the 2020 results compared to 2019 results are presented in the paragraphs below, and management's commentary for the 2019 results compared to the 2018 results are included in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission ("SEC") on February 27, 2020.

Revenue

Revenue, as compared to the prior years, was as follows:

	Year Ended December 31,			Change			
				2020		2019	
(In thousands)	2020	2019	2018	$	%	$	%
Product Sales	$ —	$ —	$ 15,304	$ —	— %	$ (15,304)	NM %
Collaboration revenue	26,464	31,250	41,791	(4,786)	(15)	(10,541)	(25)
Licensing revenue	1,500	28,500	—	(27,000)	(95)	28,500	NM
Viatris collaboration agreement	43,893	13,664	3,275	30,229	221	10,389	317
Total revenue	$ 71,857	$ 73,414	$ 60,370	$ (1,557)	(2)%	$ 13,044	22 %

NM: Not Meaningful

As a result of the sale of our VIBATIV business to Cumberland in November 2018, no product sales were recognized in 2020 and 2019.

Collaboration revenue was $26.5 million in 2020, which represented a $4.8 million decrease from 2019. Collaboration revenue was primarily comprised of revenue recognized related to the $100.0 million upfront payment received in 2018 pursuant to the Janssen collaboration agreement that was entered into in February 2018. The $4.8 million decrease was primarily attributed to a smaller portion of recognized revenue from the Janssen collaboration agreement in 2020.

Licensing revenue was $1.5 million in 2020, which represented a $27.0 million decrease from 2019. In 2019, we recognized $28.5 million in licensing revenue related to an $18.5 million upfront payment (before a required tax withholding) from Viatris associated with a June 2019 amendment for the commercialization and development rights to nebulized revefenacin in China and adjacent territories ("Viatris China Amendment") and a $10.0 million upfront payment from a Pfizer collaboration agreement for our preclinical skin-selective, locally-acting pan-JAK inhibitor program. Licensing revenue in 2020 was comprised of $1.5 million from the achievement of a milestone related to the acceptance of a clinical trial application associated with the Viatris China Amendment.

We are entitled to a share of US profits and losses (65% to Viatris; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI. In accordance with the applicable accounting guidance, amounts receivable from Viatris in connection with the commercialization of YUPELRI are recorded within the consolidated statements of operations as revenue from "Viatris collaboration agreement" irrespective of whether the overall collaboration is profitable. Amounts payable to Viatris in connection with the commercialization of YUPELRI, if any, are recorded within the consolidated statements of operations as a collaboration loss within selling, general and administrative expenses. Any reimbursement from Viatris attributed to the 65% cost-sharing of our research and development ("R&D") expenses is characterized as a reduction of R&D expense, as we do not consider performing research and development services for reimbursement to be a part of our ordinary operations.

In 2020 and 2019, we recognized $43.9 million and $13.7 million, respectively, in revenue from the Viatris collaboration agreement which represented the receivables due from Viatris related to YUPELRI. Revenue from the

Viatris collaboration agreement was $3.3 million in 2018 and represented the receivables due from Viatris during the initial channel buildout for YUPELRI in late 2018.

Cost of Goods Sold

Cost of goods sold, as compared to the prior years, was as follows:

	Year Ended December 31,			Change			
				2020		2019	
(In thousands)	2020	2019	2018	$	%	$	%
Cost of goods sold	$ —	$ —	$ 715	$ —	—%	$ (715)	NM%

NM: Not Meaningful

As a result of the sale of our VIBATIV business to Cumberland in November 2018, no cost of goods sold was recognized in 2020 and 2019.

Reduction in Workforce

In January 2019, we announced a reduction in workforce to align with our focus on continued execution of key strategic programs and advancement of selected late-stage research programs toward clinical development. We reduced our overall headcount by 51 individuals, with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV which was sold by us to Cumberland in November 2018.

The workforce reduction was substantially completed in the first quarter of 2019. We recognized and paid severance related charges totaling $3.5 million in 2019, including compensation expense made to affected employees through any minimum statutory notice periods. The severance related charges are presented on the consolidated statements of operations within research and development expenses and selling, general and administrative expenses.

Research and Development

Our 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 any reimbursements from collaboration partners, as compared to the prior years:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Employee-related	$ 60,557	$ 64,531	$ 62,896	$ (3,974)	(6)%	$ 1,635	3 %
Share-based compensation	31,294	28,953	25,563	2,341	8	3,390	13
External-related	135,114	92,921	77,305	42,193	45	15,616	20
Facilities, depreciation and other allocated expenses	33,988	32,843	35,584	1,145	3	(2,741)	(8)
Total research & development	$ 260,953	$ 219,248	$ 201,348	$ 41,705	19 %	$ 17,900	9 %

R&D expenses increased by $41.7 million in 2020 compared to 2019. The increase was due to a $42.2 million increase in external-related expenses, a $2.3 million increase in share-based compensation expenses, a $1.2 million increase in facilities, depreciation and other allocated expenses, and partially offset by a $4.0 million decrease in employee-related expenses.

The $42.2 million increase in external-related expenses was primarily due to the advancement of our priority programs, notably the continued progression of izencitinib, ampreloxetine, and TD-8236, and the initiation of the TD-0903 program in 2020. The $2.3 million increase in share-based compensation expense was primarily due to an increase in annual grants of share-based awards to employees, and the $1.2 million increase in facilities, depreciation and other allocated expenses was primarily due to an increase in allocated overhead costs. The $4.0 million decrease in employee-related expenses was primarily due to lower compensation-related expenses and lower travel and entertainment-related expenses.

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 $10.1 million, $5.6 million and $9.1 million for 2020, 2019 and 2018, respectively. The increase in expense reimbursements in 2020 compared to 2019 was primarily due to an increase in certain study activities related to izencitinib and TD-5202 that were reimbursable by our collaboration partners.

We anticipate our future R&D expenses will decrease from the current levels over the next 12 months primarily due to the planned completion of certain priority programs.

Selling, General and Administrative

Selling, general and administrative expenses, as compared to the prior years, were as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Selling, general and administrative	$ 108,661	$ 106,081	$ 97,058	$ 2,580	2 %	$ 9,023	9 %

Selling, general and administrative expenses increased by $2.6 million in 2020 compared to 2019. The increase was primarily due to a $1.6 million increase in employee-related expenses, a $1.2 million increase in external-related expenses, and a $1.1 million increase in facilities, depreciation and other allocated expenses and was partially offset by a $1.6 million decrease in YUPELRI collaboration loss.

The $1.6 million increase in employee-related expenses was primarily due to an increase in compensation-related expenses which was partially offset by lower travel and entertainment-related expenses. The $1.2 million increase in external-related expenses was primarily due to increases in costs associated with ampreloxetine and partially offset by decreases in expenses primarily related to legal and consulting services. The $1.1 million increase in facilities, depreciation and other allocated expenses was primarily due to an increase in overhead costs. The $1.6 million decrease in YUPELRI collaboration loss was due to costs incurred in early 2019 associated with the formal launch of YUPELRI.

Share-based compensation expense related to selling, general and administrative expenses was $31.7 million, $31.5 million, and $25.8 million in 2020, 2019 and 2018, respectively.

Income from Investment in TRC, LLC ("TRC")

Income from investment in TRC, as compared to the prior years, was as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Income from investment in TRC, LLC	$ 68,438	$ 33,705	$ 11,182	$ 34,733	103 %	$ 22,523	201 %

The income from investment in TRC, LLC represents our share of the royalty payments from GSK to TRC on the net sales of TRELEGY (net of our share of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters).

Income from investment in TRC increased by $34.7 million in 2020 compared to 2019. The increase was attributed to the continued sales growth of TRELEGY and an $8.5 million payment representing our share of a $10.0 million fee that GSK agreed to pay TRC upon termination of the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist program in June 2020. Our share of TRC expenses was $2.2 million and $2.7 million in 2020 and 2019, respectively, which was primarily comprised of TRC's legal and related fees associated with the arbitration cases between Innoviva and TRC and us in both years.

In connection with the issuance of our $380.0 million net principal amount Non-Recourse 2035 Notes in February 2020, 75% of the income from our investment in TRC is available only for payment of the Non-Recourse 2035 Notes and is not available to pay other creditor obligations or claims.

On June 10, 2020, we disclosed in a Form 8-K that we had formally objected to TRC and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to us under the terms of the TRC LLC Agreement. We intend to continue to seek to protect our interests in this matter consistent with the dispute resolution procedures of the TRC LLC Agreement. In this regard, we initiated an arbitration proceeding against Innoviva and TRC in October 2020 challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to us in a manner consistent with the TRC LLC Agreement and our 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. We currently anticipate a decision in those proceedings near the end of the first quarter or early in the second quarter of 2021. See *"Risk Factors – We do not control the commercialization of TRELEGY and we do not control TRC; accordingly the amount of royalties we receive will depend, among other factors, on GSK's ability to further commercialize TRELEGY and TRC's decisions concerning use of cash in accordance with the TRC LLC Agreement"* for additional information.

Interest Expense

Interest expense primarily consisted of interest payments due on the Convertible Senior 2023 Notes, the redeemed Non-Recourse 2033 Notes, and the Non-Recourse 2035 Notes, as well as, the amortization of the associated debt issuance costs. Interest expense, as compared to the comparable periods in the prior year, was as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Interest expense	$ (44,585)	$ (31,862)	$ (10,482)	$ (12,723)	40 %	$ (21,380)	204 %

Interest expense increased by $12.7 million in 2020 compared to 2019. The increase was attributed to additional interest expense related to the issuance of the Non-Recourse 2035 Notes in February 2020. As of December 31, 2020,

the net principal amount outstanding under the Non-Recourse 2035 Notes was $397.6 million at an interest rate of 9.5% compared to the retired Non-Recourse 2033 Notes which had an original net principal amount of $237.5 million and an interest rate of 9.0%.

Loss on Extinguishment of Debt

Loss on extinguishment of debt as compared to the comparable periods in the prior year, was as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Loss on extinguishment of debt	$ (15,464)	$ —	$ —	$ (15,464)	NM %	$ —	— %

NM: Not Meaningful

In 2020, we recognized a $15.5 million loss on the extinguishment of debt related to the issuance of the Non-Recourse 2035 Notes in February 2020. A portion of the proceeds from the Non-Recourse 2035 Notes were used to repay the outstanding balance of the Non-Recourse 2033 Notes that were issued in November 2018. The $15.5 million loss was comprised of a redemption premium related to the early repayment of the Non-Recourse 2033 Notes and the write-off of the previously deferred debt issuance costs related to the portion of the Non-Recourse 2033 Notes that was considered extinguished.

Interest and Other Income

Interest and other income, as compared to the prior years, was as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Interest and other income, net	$ 4,441	$ 8,395	$ 11,966	$ (3,954)	(47)%	$ (3,571)	(30)%
Costs related to GSK offering	(1,610)	—	—	(1,610)	NM	—	—
Total interest and other income, net	$ 2,831	$ 8,395	$ 11,966	$ (5,564)	(66)%	$ (3,571)	(30)%

NM: Not Meaningful

Interest and other income, net, decreased by $4.0 million in 2020 compared 2019. The decrease was primarily attributed to lower interest income earned in 2020 resulting from lower investment yields on our portfolio of marketable securities compared to 2019.

In June 2020, GSK completed its offering of $300.0 million of exchangeable senior notes due 2023, $280.3 million of which are exchangeable into our ordinary shares that are held by a subsidiary of GSK. We will not be issuing any new ordinary shares in connection with the GSK offering, and we did not receive any proceeds from the GSK offering. We incurred $1.6 million in costs, primarily comprised of financial advisory, accounting and legal-related costs.

Provision for Income Tax (Expense) Benefit

The provision for income tax, as compared to the prior years, was as follows:

	Year Ended December 31,			Change 2020		Change 2019	
(In thousands)	2020	2019	2018	$	%	$	%
Provision for income tax benefit	$ 8,520	$ 5,222	$ 10,561	$ 3,298	63 %	$ (5,339)	(51)%

The 2020 and 2019 benefits for income taxes of $8.5 million and $5.2 million, respectively, were primarily due to the reversals of previously accrued contingent tax liabilities for uncertain tax positions due to a lapse of the statute of limitations.

Liquidity and Capital Resources

To date, we have financed our operations primarily through public offering of equity and debt securities, private placements of equity and debt, revenue from collaboration and licensing arrangements and, to a lesser extent, revenue from product sales. As of December 31, 2020, we had approximately $292.9 million in cash, cash equivalents, and investments in marketable securities (excluding restricted cash). Also, as of December 31, 2020, we had outstanding (i) $230.0 million in principal Convertible Senior 2023 Notes and (ii) $397.6 million in principal Non-Recourse 2035 Notes which are stated net of a 5.0% retention by us in compliance with Regulation RR — Credit Risk Retention (17 C.F.R. Part 246).

The Non-Recourse 2035 Notes were issued on February 28, 2020 and are secured by all of the Triple Royalty Sub II LLC's (the "Issuer II") rights, title and interest as a holder of the Issuer II Class C Units in TRC. The primary source of funds to make payments on the Non-Recourse 2035 Notes is the 63.75% economic interest of the Issuer (evidenced by the Issuer II Class C Units) in any future payments that may be made by GSK to TRC under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters) relating to the GSK-Partnered Respiratory Programs, including the TRELEGY program. As a result, the holders of the Non-Recourse 2035 Notes have no recourse against Theravance Biopharma even if the TRELEGY payments are insufficient to cover the principal and interest payments for the Non-Recourse 2035 Notes. Prior to and including the December 5, 2024 payment date, in the event that the distributions received by the Issuer II from TRC in a quarter is less than the interest accrued for that quarter, the principal amount of the Non-Recourse 2035 Notes will increase by the interest shortfall amount for that quarter. While the holders of the Non-Recourse 2035 Notes have no recourse against Theravance Biopharma, the terms of the Non-Recourse 2035 Notes also provide that Theravance Biopharma, at its option, may satisfy the quarterly interest payment obligations by making a capital contribution to the Issuer II.

A portion of the proceeds from the Non-Recourse 2035 Notes issuance were used to repay, in full, the remaining outstanding balance of the Non-Recourse 2033 Notes, as well as, a 5% premium on the early redemption of the Non-Recourse 2033 Notes. The Non-Recourse 2033 Notes were issued in November 2018 and were structured similarly to the Non-Recourse 2035 Notes.

On February 14, 2020, we sold 5,500,000 ordinary shares at a price to the public of $27.00 per share (the "Shares"). The gross proceeds from the offering were $148.5 million, before deducting underwriting discounts and commissions and estimated offering expenses. The Shares were issued pursuant to our currently effective shelf registration statement on Form S-3, which became effective automatically on December 3, 2019, and a prospectus supplement filed with the SEC in connection with the offering.

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 and commercialization costs relating to YUPELRI. 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 may continue to receive potential substantial payments from future collaboration transactions if the drug candidates in our pipeline achieve positive clinical or regulatory outcomes or if our product candidates are approved and meet certain milestones. Our current business plan is subject to significant uncertainties and risks as a result of, among other factors, the COVID-19 pandemic, 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 any approved products, 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 be sufficient to fund our operations for at least the next 12 months from the issuance date of these consolidated financial statements based on current operating plans and financial forecasts.

We may seek to obtain additional financing in the form of public or private equity offerings, debt financing or additional collaborations and licensing arrangements. However, future financing may not be available in amounts or on terms acceptable to us.

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 preclinical 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 prior years, were as follows:

	Year Ended December 31,			Change	
(In thousands)	**2020**	**2019**	**2018**	**2020**	**2019**
Net cash used in operating activities	$ (250,403)	$ (238,197)	$ (112,867)	$ (12,206)	$ (125,330)
Net cash provided by (used in) investing activities	10,721	(83,051)	176,708	93,772	(259,759)
Net cash provided by financing activities	263,085	1,291	225,200	261,794	(223,909)

Net cash flows used in operating activities

Net cash used in operating activities was $250.4 million in 2020, consisting primarily of a net loss of $278.0 million, a net increase in cash resulting from adjustments for total non-cash and other reconciling items of $67.1 million and a net decrease in cash resulting from changes in operating assets and liabilities of $39.5 million.

Net cash used in operating activities was $238.2 million in 2019, consisting primarily of a net loss of $236.5 million, a net increase in cash resulting from adjustments for total non-cash and other reconciling items of $43.7 million and a net decrease in cash resulting from changes in operating assets and liabilities of $45.4 million.

Net cash flows provided by (used in) investing activities

Net cash provided by investing activities was $10.7 million in 2020 and was primarily attributed the proceeds from the sales of marketable securities of $19.9 million which was partially offset by (i) $6.6 million related to the purchase of property and equipment and (ii) $2.7 million in cash outflows resulting from net purchases and maturities of marketable securities.

Net cash used in investing activities was $83.1 million in 2019 and was primarily attributed to cash outflows resulting from net purchases and maturities of marketable securities of $84.9 million.

Net cash flows provided by financing activities

Net cash provided by financing activities was $263.1 million in 2020, consisting primarily of the sale of 5,500,000 ordinary shares for total net proceeds of $139.9 million and the issuance of our Non-Recourse 2035 Notes for total net proceeds of $374.7 million. A portion of the of the Non-Recourse 2035 Notes proceeds were used to repay, in full, the remaining $235.3 million outstanding balance of our Non-Recourse 2033 Notes and an $11.5 million

redemption premium related to the payoff of the Non-Recourse 2033 Notes. In addition to the above, net cash provided by financing activities was partially offset by the repurchase of shares to satisfy tax withholding obligations in the amount of $9.7 million.

Net cash provided by financing activities was $1.3 million in 2019, consisting of $6.6 million of cash inflows from employee share plan purchase proceeds and share option exercises which was partially offset by $3.2 million of net cash outflows related to the repurchase of shares to satisfy tax withholding obligations and $2.1 million of net cash outflows related to the principal paydown of our Non-Recourse 2033 Notes.

Contractual Obligations and Commercial Commitments

In the table below, we set forth our significant obligations and future commitments, as well as obligations related to all contracts that we are likely to continue, regardless of the fact that they were cancelable as of December 31, 2020. Some of the figures that we include in this table are based on management's estimate and assumptions about these obligations, including their duration. Because these estimates and assumptions are necessarily subjective, the amount of the obligations we will actually pay in future periods may vary from those reflected in the table.

		Years			
(In thousands)	**Total**	**Within 1**	**Over 1 to 3**	**Over 3 to 5**	**After 5**
3.25% Convertible senior notes due 2023 - principal	$ 230,000	$ —	$ 230,000	$ —	$ —
3.25% Convertible senior notes due 2023 - interest	21,200	7,475	13,725	—	—
9.5% Non-recourse notes due 2035 - net principal *	397,643	*	*	*	*
Facility operating leases (1)	99,683	9,522	19,852	21,000	49,309
Purchase obligations (2)	311,181	152,881	84,611	64,876	8,813
Total	$ 1,059,707	$ 169,878	$ 348,188	$ 85,876	$ 58,122

* The Non-Recourse 2035 Notes are secured by the Issuer II's right, title, and interest in TRC. The primary source of funds to make payments on the Non-Recourse 2035 Notes is the 63.75% economic interest of the Issuer II in any future payments made by GSK under the collaboration agreement, dated as of November 14, 2002, by and between Innoviva and GSK relating to the TRELEGY program. In addition, prior to December 5, 2024, in the event that the distributions received by the Issuer II from TRC in a quarter is less than the interest accrued for the quarter, the principal amount of the Non-Recourse 2035 Notes will increase by the interest shortfall amount for that period. Since the timing of the principal and interest payments on the Non-Recourse 2035 Notes are ultimately based on royalties from TRELEGY product sales, which will vary from quarter to quarter and are unknown to us, only the total net principal payment amount at issuance is included in the above table. See "*Item 8, Note 7. Debt*" of the accompanying consolidated financial statements for further information.

(1) As security for performance of certain obligations under the operating leases for our principal physical properties, we issued a letter of credit in the amount of $0.8 million, collateralized by an equal amount of restricted cash.

(2) Substantially all of this amount was subject to open purchase orders, as of December 31, 2020, that were issued under existing contracts. This amount does not represent any minimum contract termination liabilities for our existing contracts.

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 December 31, 2020.

Performance-Contingent Awards

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 meeting certain operating goals and objectives during the five-year period from 2016 to December 31, 2020. These goals are strategically important for us, and we believe the goals should 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. We recognize compensation expense relating to awards subject to performance conditions if it is considered probable that the performance goals will be achieved. The probability of achievement is reassessed at each quarter-end reporting period. Previously recognized expense is reversed in the period in which it becomes probable that the requisite service period will not be rendered.

We determined that achievement of the requisite performance conditions for the first tranche was completed in June 2018, and the expense associated with this first tranche was fully recognized in 2018. We determined that achievement of the requisite performance conditions for the second tranche were completed in February 2019, and the expense associated with this second tranche was fully recognized as of March 31, 2020. For the year ended December 31, 2020, we recognized $0.4 million and $0.5 million of share-based compensation expense and cash bonus expense, respectively, related to the second tranche of these awards.

In February 2020, we determined that the requisite performance conditions for the third tranche were completed. For the year ended December 31, 2020, we recognized $2.6 million and $2.8 million of share-based compensation expense and cash bonus expense, respectively, related to the third tranche of these awards. As of December 31, 2020, the maximum remaining share-based compensation expense and cash bonus expense associated with the third tranche was $0.4 million each.

Separate from the performance-contingent awards described above, we periodically grant performance-contingent RSUs to individual employees. For the year ended December 31, 2020, we recognized $1.0 million of share-based compensation expense related to such awards. As of December 31, 2020, there were 70,000 shares of these performance-contingent RSUs outstanding that have a maximum remaining share-based compensation expense of $0.5 million with performance expiration dates through June 2022.

Off-Balance Sheet Arrangements

Our equity interest in TRC constitutes an off-balance sheet arrangement. Under the agreement governing TRC, the manager of TRC may request quarterly capital contributions from us to fund the operating costs of TRC; however, we are not obligated to make such contributions. Our equity interest in TRC entitles us to an 85% economic interest in any future payments, which includes royalties and milestone payments, made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC by Innoviva (the "GSK Agreements"). We have determined TRC to be a variable interest entity that is not consolidated in our financial statements. The potential importance of TRC to our future financial condition and results of operations is dependent upon the progression of drug candidates covered by the GSK Agreements through development to commercialization and the rate of commercialization for approved drugs covered by the GSK Agreements. We rely on publicly available information about those drug candidates as we do not have access to confidential information regarding their progression or status.

Recent Accounting Pronouncements

The information required by this item is included in *"Item 8, Note 1. Organization and Summary of Significant Accounting Policies,"* in our consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities.

Interest Rate Sensitivity

We have invested primarily in money market funds, federal agency notes, corporate debt securities, commercial papers and US treasury notes. To reduce the volatility relating to these exposures, we have put investment and risk management policies and procedures in place. The securities in our investment portfolio are not leveraged and are classified as available-for-sale due to their short-term nature. We currently do not engage in hedging activities.

We performed a sensitivity analysis to determine the impact a change in interest rates would have on the value of our investment portfolio. As of December 31, 2020 and 2019, we have estimated that a hypothetical 100 basis point increase in interest rates would have resulted in a decrease in the fair market value of our investment portfolio of $0.5 million and $0.8 million, respectively. Such losses would only be realized if we sold the investments prior to maturity.

We are also subject to interest rate sensitivity on our outstanding Convertible Senior 2023 Notes that were issued in November 2016 and our Non-Recourse 2035 Notes that were issued in February 2020. Increases in interest rates would result in a decrease in the fair value of our outstanding debt and decreases in interest rates would result in an increase in the fair value of our outstanding debt. These decreases or increases in the fair value of our outstanding debt would be partially offset by corresponding decreases or increases in our fixed income investment portfolio. The Convertible Senior 2023 Notes pay interest semi-annually, and the $230.0 million of principal is scheduled to be repaid in 2023. The Non-Recourse 2035 Notes pay interest and principal quarterly, and the remaining net principal of $397.6 million is due by 2035.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Theravance Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Theravance Biopharma, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, shareholders' deficit, and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue from collaborative and licensing arrangements

Description of the Matter	The Company recognized revenue from collaboration and licensing agreements of $71.9 million for the year ended December 31, 2020. As described in Note 1, collaboration payment structures may include many elements such as up-front fees, milestones, royalties, expense reimbursement, and/or profit sharing. Furthermore, collaborations may include the delivery of various goods or services to the collaborative partner such as licenses to intellectual property or research and development services. In some circumstances, management is required to use judgment to determine whether analogies to the revenue accounting literature are appropriate for elements of collaboration

arrangements. Of the $71.9 million recognized as collaboration revenue, $26.4 million was recognized for research and development services under the agreement with Janssen Biotech, Inc. (the "Janssen Agreement") based on a measure of the Company's efforts toward satisfying performance obligations relative to the total expected efforts or inputs to satisfy such performance obligations (e.g., costs incurred compared to total budget).

Auditing the Company's accounting for revenues from collaboration arrangements was especially challenging due to the complex and highly judgmental nature of evaluating the terms of the related agreements, identifying performance obligations, evaluating whether analogies to the revenue accounting guidance are appropriate, determining and allocating the transaction price to the performance obligations, evaluating estimates of the expected efforts to complete performance obligations and measuring efforts toward satisfying those performance obligations, especially as such measuring of efforts relates to the Janssen Agreement.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's processes for assessing the accounting treatment of any new collaboration agreements or modifications to existing collaboration agreements, establishing an estimated budget of costs, assessing the effort to satisfy performance obligations, and recording actual costs incurred including controls over the completeness and accuracy of data used in the underlying analysis.

To test the accounting for revenue from collaboration arrangements we tested and evaluated, among other things, the performance obligations identified, the estimates and assumptions used to determine transaction price, and the allocation of transaction price to performance obligations. We assessed whether management's analogies to the revenue literature were a consistent and rational application of accounting policy. To test the measurement of efforts toward satisfying performance obligations, our audit procedures included, among others, reviewing management's analysis for accuracy and completeness by agreeing data to underlying agreements and inspecting communications with collaboration partners. Our audit procedures specific to the recognition of revenue under the Janssen Agreement focused on evaluating the measure of progress based on costs incurred including performing corroborative inquiries with those outside of the finance department, performing sensitivity analyses of key inputs, evaluating the historical accuracy of management's budgeted cost estimates, and inspecting evidence of actual costs incurred.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.
Redwood City, California
February 26, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 81,467	$ 58,064
Short-term marketable securities	211,474	222,767
Receivables from collaborative arrangements	15,868	11,996
Receivables from licensing arrangements	—	10,000
Amounts due from TRC, LLC	53,799	28,574
Prepaid clinical and development services	20,374	2,736
Other prepaid and current assets	10,359	4,351
Total current assets	393,341	338,488
Property and equipment, net	16,422	12,644
Long-term marketable securities	—	4,985
Operating lease assets	43,260	46,604
Equity in net assets of TRC, LLC	12,750	—
Tax receivable	—	3,682
Restricted cash	833	833
Other assets	2,451	1,590
Total assets	$ 469,057	$ 408,826
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 6,775	$ 4,758
Accrued personnel-related expenses	35,238	28,180
Accrued clinical and development expenses	28,799	17,587
Accrued general and administrative expenses	6,048	4,394
Accrued interest payable	3,974	5,659
Current portion of non-recourse notes due 2035, net	19,334	—
Current portion of non-recourse notes due 2033, net	—	9,851
Operating lease liabilities	9,867	7,762
Deferred revenue	11,523	31,575
Other accrued liabilities	2,013	1,937
Total current liabilities	123,571	111,703
Convertible senior notes due 2023, net	226,963	225,890
Non-recourse notes due 2035, net	372,873	—
Non-recourse notes due 2033, net	—	219,300
Long-term operating lease liabilities	47,220	47,725
Long-term deferred revenue	348	6,761
Other long-term liabilities	1,833	21,287
Commitments and contingencies		
Shareholders’ Deficit		
Preferred shares, $0.00001 par value: 230 shares authorized, no shares issued or outstanding	—	—
Ordinary shares, $0.00001 par value: 200,000 shares authorized; 64,328 and 57,015 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	1,222,818	1,024,614
Accumulated other comprehensive income	47	145
Accumulated deficit	(1,526,617)	(1,248,600)
Total shareholders’ deficit	(303,751)	(223,840)
Total liabilities and shareholders’ deficit	$ 469,057	$ 408,826

See accompanying notes to consolidated financial statements

THERAVANCE BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
Revenue:			
Product sales	$ —	$ —	$ 15,304
Collaboration revenue	26,464	31,250	41,791
Licensing revenue	1,500	28,500	—
Viatris collaboration agreement	43,893	13,664	3,275
Total revenue	71,857	73,414	60,370
Costs and expenses:			
Cost of goods sold	—	—	715
Research and development (1)	260,953	219,248	201,348
Selling, general and administrative (1)	108,661	106,081	97,058
Total costs and expenses	369,614	325,329	299,121
Loss from operations	(297,757)	(251,915)	(238,751)
Income from investment in TRC, LLC	68,438	33,705	11,182
Interest expense	(44,585)	(31,862)	(10,482)
Loss on extinguishment of debt	(15,464)	—	—
Interest and other income, net	2,831	8,395	11,966
Loss before income taxes	(286,537)	(241,677)	(226,085)
Provision for income tax benefit	8,520	5,222	10,561
Net loss	$ (278,017)	$ (236,455)	$ (215,524)
Net loss per share:			
Basic and diluted net loss per share	$ (4.46)	$ (4.25)	$ (3.99)
Shares used to compute basic and diluted net loss per share	62,345	55,610	53,969

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Research and development	$ 31,294	$ 28,953	$ 25,563
Selling, general and administrative	31,682	31,497	25,750
Total share-based compensation expense	$ 62,976	$ 60,450	$ 51,313

See accompanying notes to consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,		
	2020	2019	2018
Net loss	$ (278,017)	$ (236,455)	$ (215,524)
Other comprehensive income (loss):			
Net unrealized gain (loss) on available-for-sale investments, net of tax	(98)	311	567
Comprehensive loss	$ (278,115)	$ (236,144)	$ (214,957)

See accompanying notes to consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
(In thousands)

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Deficit
Balances at December 31, 2017	54,381	$ 1	$ 913,650	$ (733)	$ (797,740)	$ 115,178
Proceeds from ESPP purchases	204	—	4,173	—	—	4,173
Employee share-based compensation expense	—	—	51,313	—	—	51,313
Issuance of restricted shares	1,168	—	—	—	—	—
Option exercises	75	—	1,393	—	—	1,393
Cumulative effect upon the adoption of ASC 606	—	—	—	—	1,119	1,119
Repurchase of shares to satisfy tax withholding	(147)	—	(9,808)	—	—	(9,808)
Net unrealized gain on marketable securities	—	—	—	567	—	567
Net loss	—	—	—	—	(215,524)	(215,524)
Balances at December 31, 2018	55,681	$ 1	$ 960,721	$ (166)	$ (1,012,145)	$ (51,589)

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Deficit
Balances at December 31, 2018	55,681	$ 1	$ 960,721	$ (166)	$ (1,012,145)	$ (51,589)
Proceeds from ESPP purchases	203	—	3,474	—	—	3,474
Employee share-based compensation expense	—	—	60,450	—	—	60,450
Issuance of restricted shares	1,105	—	—	—	—	—
Option exercises	164	—	3,142	—	—	3,142
Repurchase of shares to satisfy tax withholding	(138)	—	(3,173)	—	—	(3,173)
Net unrealized gain on marketable securities	—	—	—	311	—	311
Net loss	—	—	—	—	(236,455)	(236,455)
Balances at December 31, 2019	57,015	$ 1	$ 1,024,614	$ 145	$ (1,248,600)	$ (223,840)

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Deficit
Balances at December 31, 2019	57,015	$ 1	$ 1,024,614	$ 145	$ (1,248,600)	$ (223,840)
Net proceeds from sale of ordinary shares	5,500	—	139,915	—	—	139,915
Proceeds from ESPP purchases	245	—	3,701	—	—	3,701
Employee share-based compensation expense	—	—	62,976	—	—	62,976
Issuance of restricted shares	1,907	—	—	—	—	—
Option exercises	68	—	1,361	—	—	1,361
Repurchase of shares to satisfy tax withholding	(407)	—	(9,749)	—	—	(9,749)
Net unrealized loss on marketable securities	—	—	—	(98)	—	(98)
Net loss	—	—	—	—	(278,017)	(278,017)
Balances at December 31, 2020	64,328	$ 1	$ 1,222,818	$ 47	$ (1,526,617)	$ (303,751)

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2020	**2019**	**2018**
Operating activities			
Net loss	$ (278,017)	$ (236,455)	$ (215,524)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,798	6,441	4,481
Amortization and accretion income, net	(1,079)	(3,451)	(1,315)
Share-based compensation	62,976	60,450	51,313
Net gain from the sale of VIBATIV business	—	—	(6,056)
Amortization of right-of-use assets	3,344	3,224	—
Undistributed earnings from TRC, LLC	(37,975)	(23,152)	(5,152)
Interest shortfall on 2035 notes, net	17,643	—	—
Loss on extinguishment of debt	15,464	—	—
Other	(95)	146	(43)
Changes in operating assets and liabilities:			
Accounts receivable	—	620	1,633
Receivables from collaborative and licensing arrangements	6,128	(11,943)	(2,944)
Prepaid clinical and development services	(17,638)	(561)	(2,175)
Other prepaid and current assets	(2,327)	(73)	(225)
Inventory	—	—	(1,629)
Tax receivable	(258)	(3,700)	8,191
Other assets	(852)	(358)	45
Accounts payable	3,658	(4,274)	3,575
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	5,983	10,626	(12,357)
Accrued interest payable	(1,685)	2,573	1,841
Deferred rent	—	—	4,308
Deferred revenue	(26,465)	(31,245)	69,224
Operating lease liabilities	1,600	(2,317)	—
Other long-term liabilities	(7,606)	(4,748)	(10,058)
Net cash used in operating activities	(250,403)	(238,197)	(112,867)
Investing activities			
Purchases of property and equipment	(6,616)	(3,176)	(7,240)
Purchases of marketable securities	(401,987)	(423,898)	(183,261)
Maturities of marketable securities	399,318	339,018	347,192
Proceeds from the sale of marketable securities	19,942	—	—
Proceeds from the sale of property and equipment	64	5	17
Proceeds from the sale of VIBATIV business, net	—	5,000	20,000
Net cash provided by (used in) investing activities	10,721	(83,051)	176,708
Financing activities			
Proceeds from the sale of ordinary shares, net	139,915	—	—
Proceeds from issuance of 2035 notes, net	380,000	—	—
Payment of issuance costs on 2035 notes	(5,326)	—	—
Proceeds from issuance of 2033 notes, net	—	—	229,441
Payment of redemption premium on 2033 notes	(11,470)	—	—
Principal payment on 2033 notes	(235,347)	(2,152)	—
Proceeds from ESPP purchases	3,701	3,474	4,173
Proceeds from option exercises	1,361	3,142	1,393
Repurchase of shares to satisfy tax withholding	(9,749)	(3,173)	(9,807)
Net cash provided by financing activities	263,085	1,291	225,200
Net increase (decrease) in cash, cash equivalents, and restricted cash	23,403	(319,957)	289,041
Cash, cash equivalents, and restricted cash at beginning of period	58,897	378,854	89,813
Cash, cash equivalents, and restricted cash at end of period	$ 82,300	$ 58,897	$ 378,854
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 24,024	$ 26,178	$ 7,475
Cash paid (received) for income taxes, net	$ 14	$ 22	$ (7,316)
Right-of-use assets obtained in exchange for lease obligations (1)	$ —	$ 49,847	$ —

(1) Amounts for the year ended December 31, 2019 include the transition adjustment for the adoption of ASC 842, *Leases*.

See accompanying notes to consolidated financial statements.

THERAVANCE BIOPHARMA, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Theravance Biopharma, Inc. (“Theravance Biopharma” or the “Company”) is a diversified biopharmaceutical company primarily focused on the discovery, development and commercialization of organ-selective medicines. The Company’s purpose is to create transformational medicines to improve the lives of patients suffering from serious illnesses. The Company’s research is focused in the areas of inflammation and immunology.

Basis of Presentation

The Company’s consolidated financial statements as of December 31, 2020 and 2019, and for the year ended December 31, 2020, 2019, and 2018 have been prepared in conformity with United States (“US”) Generally Accepted Accounting Principles ("GAAP"), and the US Securities and Exchange (“SEC”) regulations for annual reporting.

Principles of Consolidation

The consolidated financial statements include the accounts of Theravance Biopharma and its wholly-owned subsidiaries, all of which are denominated in US dollars. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Segment Reporting

The Company operates in a single segment, which is the discovery (research), development and commercialization of human therapeutics. The Company’s business offerings have similar economics and other characteristics, including the nature of products and manufacturing processes, types of customers, distribution methods and regulatory environment. The Company is comprehensively managed as one business segment by the Company’s Chief Executive Officer and the management team. Product sales, if any, are attributed to regions based on ship-to location and revenue from collaborative arrangements, including royalty revenue, are attributed to regions based on the location of the collaboration partner. Revenue from profit sharing-type arrangements is attributed to the geographic market in which the products are sold. Capitalized property and equipment is predominantly located in the US.

Cash and Cash Equivalents

The Company considers all highly-liquid investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents are carried at fair value.

Restricted Cash

The Company maintains restricted cash for certain lease agreements and letters of credit by which the Company has pledged cash and cash equivalents as collateral. The Company may also maintain restricted cash for debt servicing of its non-recourse notes. See *“Note 5. Cash, Cash Equivalents, and Restricted Cash”* for more information.

Investments in Marketable Securities

The Company invests in marketable securities, primarily corporate notes, government bonds and government agency bonds. The Company classifies its marketable securities as available-for-sale securities and reports them at fair value in cash and cash equivalents or marketable securities on the consolidated balance sheets with related unrealized

gains and losses included as a component of shareholders' deficit. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest and other income (loss) on the consolidated statements of operations. The cost of securities sold is based on the specific identification method. Realized gains and losses and interest and dividends on securities are included in interest and other income (loss).

The Company accounts for credit losses on available-for-sale debt securities in accordance with Accounting Standards Codification ("ASC"), Topic 326, *Financial Instruments – Credit Losses* ("ASC 326"). Under ASC 326, the Company regularly reviews its investments for declines in estimated fair value below amortized cost. The factors considered in determining whether a credit loss exists include the creditworthiness of the security issuers, the number of securities in unrealized loss positions, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of the security's amortized cost basis.

In circumstances where the Company intends to sell, or is more likely than not required to sell, the security before it recovers its amortized cost basis, the difference between fair value and amortized cost is recognized as a loss in the consolidated statements of operations, with a corresponding write-down of the security's amortized cost. In circumstances where neither condition exists, the Company then evaluates whether a decline is due to credit-related factors. To determine the portion of a decline in fair value that is credit-related, the Company compares the present value of the expected cash flows of the security discounted at the security's effective interest rate to the amortized cost basis of the security. A credit-related impairment is limited to the difference between fair value and amortized cost and recognized as an allowance for credit loss on the consolidated balance sheets with a corresponding adjustment to net income (loss). Any remaining decline in fair value that is non-credit related is recognized in other comprehensive loss, net of tax. Improvements in expected cash flows due to improvements in credit are recognized through reversal of the credit loss and corresponding reduction in the allowance for credit loss.

Fair Value of Financial Instruments

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies these inputs into the following hierarchy:

Level 1 — Quoted prices for identical instruments in active markets.

Level 2 — 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.

Level 3 — Unobservable inputs and little, if any, market activity for the assets.

Financial instruments include cash equivalents, marketable securities, accounts receivable, accounts payable, accrued liabilities and debt. The Company's cash equivalents and marketable securities are carried at estimated fair value and remeasured on a recurring basis. The carrying value of accounts receivable, receivables from collaborative arrangements, accounts payable and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments. The fair value of the Company's debt is classified as a level 2 financial instrument and is disclosed in *"Note 7. Debt"*.

Accounts Receivable

For the periods presented, the Company's accounts receivable primarily relate to amounts due arising from its collaboration and licensing agreements. When appropriate, the Company provides for an allowance for specifically

identified doubtful accounts. The Company performs periodic credit evaluations of its customers and generally does not require collateral. For the periods presented, the Company did not have any material write-offs of accounts receivable

Concentration of Credit Risks

The Company invests in a variety of financial instruments and, based on its policy, limits the amount of credit exposure with any one issuer, industry or geographic area for investments other than instruments backed by the US federal government.

The Company's receivables primarily relate to amounts due under its collaboration and licensing agreements. Accordingly, the Company may be exposed to credit risk generally associated with pharmaceutical companies or specific to its collaboration agreements. The Company performs periodic evaluations of its customers and generally does not require collateral. For the year ended December 31, 2020, 2019, and 2018, the Company did not experience any material losses related to its receivables.

Property and Equipment

Property, equipment and leasehold improvements are stated at cost, net of accumulated depreciation, and amortized using the straight-line method as follows:

Leasehold improvements	Shorter of remaining lease terms or useful life
Equipment, furniture and fixtures	5 - 7 years
Software and computer equipment	3 - 5 years

Leases

The Company determines whether a contract is or contains a lease at inception of the arrangement. In evaluating whether a contract is indicative of a lease, the Company considers all relevant facts and circumstances to assess whether the arrangement has extended to the Company the right to both (i) obtain substantially all the economic benefits from use of an identified asset and (ii) direct the use of the identified asset. To the extent that the Company determines a contract represents a lease, the arrangement is classified as either an operating lease or a finance lease, with the classification affecting the presentation and pattern of expense recognition in the consolidated statements of operations. The Company did not have any finance leases at either December 31, 2020 or 2019.

Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the leasing arrangement. The Company records operating leases on the consolidated balance sheets through an operating lease asset and a corresponding short-term and long-term operating lease liability, as applicable. Lease liabilities are measured based on the present value of lease payments over the lease term discounted at the implicit interest rate, when readily available or using the Company's incremental borrowing rate, if the implicit rate is not determinable. The incremental borrowing rate is considered the rate of interest that the Company would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. The Company measures its operating lease assets based on the corresponding operating lease liabilities adjusted for (i) prepayments made to the lessor at or before the commencement date, (ii) any initial direct costs incurred, and (iii) tenant incentives granted under the lease contract.

In calculating operating lease assets and liabilities, the Company may elect to combine lease and non-lease components based on the asset type. The Company's lease terms may include options to extend the lease only when it is reasonably certain that such options will be exercised, and the Company recognizes lease expense on a straight-line basis over the lease term. Operating lease assets are evaluated for possible impairment in accordance with the Company's long-lived assets policy.

The Company does not recognize operating lease assets or liabilities for leases that have a lease term of 12 months or less at commencement date, and the lease expense related to these short-term lease arrangements is recognized on a straight-line basis over the term of the lease.

Capitalized Software

The Company capitalizes certain costs related to direct material and service costs for software obtained for internal use. Upon being placed in service, these costs and other future capitalizable costs related to the internal use software system integration are depreciated over five years. There were no material capitalized software costs recorded for the year ended December 31, 2020 or 2019.

Impairment of Long-Lived Assets

The Company's long-lived assets consists of property and equipment, operating lease assets and other assets. The carrying value of long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss is recognized when the total of estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. There were no impairments of long-lived assets recorded for the year ended December 31, 2020, 2019 or 2018.

Revenue Recognition

The Company recognizes revenue under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). 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, an 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, the Company identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Collaborative Arrangements under ASC 606

The Company enters into collaborative arrangements with partners that fall under the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of these arrangements. The Company analogizes to ASC 606 for certain activities within collaborative arrangements for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations. Revenue recognized by analogizing to ASC 606 is recorded as "collaboration revenue" or "licensing revenue" whereas, revenue recognized in accordance with ASC 808 is recorded on a separate collaboration revenue line on the consolidated statements of operations.

The terms of the Company's collaborative 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 research and development expenses; and (v) profit/loss sharing arising from co-promotion arrangements. Each of these payments results in collaboration revenues or an offset against research and development expense. Where a portion of non-refundable up-front fees or other payments received is allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

As part of the accounting for these arrangements, the Company 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. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the collaborative partner 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.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes collaboration 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, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when the Company receives up-front fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, the Company recognizes collaboration revenue for those units of account over time using a measure of progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts 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), the Company evaluates whether the milestones are considered probable of being reached and estimates 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 the Company's or the collaborative 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, the Company re-evaluates the probability of achievement of milestones that are within its or the collaborative partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its 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 the Company's 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, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Following the sale of VIBATIV to Cumberland Pharmaceuticals Inc. ("Cumberland") in November 2018, VIBATIV royalties earned from Cumberland are included within "interest and other income, net" on the consolidated statements of operations. In addition, the Company's income earned related to TRELEGY sales is included within "income from investment in TRC, LLC" on the consolidated statements of operations.

Reimbursement, cost-sharing and profit-sharing payments: Under certain collaborative arrangements, the Company has been reimbursed for a portion of its research and development expenses or participates in the cost-sharing of such research and development expenses. Such reimbursements and cost-sharing arrangements have been reflected as a reduction of research and development expense in the Company's consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations.

Product Sales

In November 2018, the Company completed the sale of its assets related to the manufacture, marketing and sale of the VIBATIV product to Cumberland. Up until that date, the Company sold VIBATIV in the US market by making the drug product available through a limited number of distributors, who sold VIBATIV to healthcare providers. Title and risk of loss transferred upon receipt by these distributors. The Company recognized VIBATIV product sales and related cost of product sales when the distributors obtained control of the drug product, which was at the time title transferred to the distributors.

The Company recorded sales on a net sales basis which included estimates of variable consideration. The variable consideration resulted from sales discounts, government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions for sales made by the Company prior to the November 2018 sale to Cumberland. The Company reflected 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 were based on management's estimates that considered payor mix in target markets, industry benchmarks and historical experience. In general, these estimates took into consideration a range of possible outcomes which were probability-weighted in accordance with the expected value method in ASC 606. The Company monitored inventory levels in the distribution channel, as well as sales by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances were based on amounts owed or to be claimed on related sales. These estimates took into consideration the terms of the Company's agreements with customers, historical product returns, 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. The Company updated its estimates and assumptions each quarter and if actual future results varied from its estimates, the Company adjusted these estimates, which could have had an effect on product sales and earnings in the period of adjustment.

Research and Development Expenses

Research and development ("R&D") expenses are recorded in the period that services are rendered or goods are received. R&D expenses consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain R&D activities on behalf of the Company, net of certain external R&D expenses reimbursed under the Company's collaborative arrangements.

As part of the process of preparing its consolidated financial statements, the Company is required to estimate and accrue certain R&D expenses. This process involves the following:

- identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in the Company's consolidated financial statements as of each balance sheet date based on facts and circumstances known to it at the time; and
- periodically confirming the accuracy of the Company's estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that the Company accrues include:

- fees paid to clinical research organizations ("CROs") in connection with preclinical and toxicology studies and clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturing organizations ("CMOs") in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

The Company bases its expense accruals related to clinical studies on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical studies on the Company's behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. The Company's service providers typically invoice it

monthly in arrears for services performed. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the Company does not identify costs that it has begun to incur or if it underestimates or overestimates the level of services performed or the costs of these services, the Company's actual expenses could differ from its estimates.

To date, the Company has not experienced significant changes in its estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, there is no assurance that the Company will not make changes to its estimates in the future as it becomes aware of additional information about the status or conduct of its clinical studies and other research activities. Such changes in estimates will be recognized as research and development expenses in the period that the change in estimate occurs.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $6.3 million, $2.4 million and $1.9 million for the year ended December 31, 2020, 2019 and 2018, respectively.

Fair Value of Share-Based Compensation Awards

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire shares granted under its employee share purchase plan ("ESPP"). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected share price volatility. The Company uses the "simplified" method as described in Staff Accounting Bulletin No. 107, *Share-Based Payment*, to estimate the expected option term.

Share-based compensation expense is calculated based on awards ultimately expected to vest and is reduced for actual forfeitures as they occur. Compensation expense for purchases under the ESPP is recognized based on the fair value of the award on the date of offering.

Debt Instruments

Coupon interest on the Company's debt instruments is accrued using the effective interest rate method over the estimated period the debt will be repaid. Debt issuance costs are capitalized as deferred financing costs and presented as a reduction of the carrying value of the financial liability on the Company's consolidated balance sheets. Debt issuance costs subsequently are amortized to interest expense over the estimated life of the related debt based on the effective interest method. The Company considers whether there are any embedded features in its debt instruments that require bifurcation and separate accounting as derivative financial instruments pursuant to ASC Topic 815, *Derivatives and Hedging*. As of December 31, 2020 and 2019, the Company's debt instruments did not include any features that require bifurcation and separate derivative accounting.

Theravance Respiratory Company, LLC ("TRC")

Through the Company's 85% equity interest in TRC, the Company is entitled to receive an 85% economic interest in any future payments made by Glaxo Group or one of its affiliates ("GSK") under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The primary drug program assigned to TRC is TRELEGY.

The Company analyzed its ownership, contractual and other interests in TRC to determine if TRC is a variable-interest entity ("VIE"), whether the Company has a variable interest in TRC and the nature and extent of that interest. The Company 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, the Company also assessed whether the Company is the primary beneficiary of TRC based on the power to direct its activities that most significantly impact its economic performance and the Company's obligation to absorb its losses or the right to receive benefits from it that could potentially be significant to TRC. Based on the Company's assessment, it determined that it is not the primary beneficiary of TRC, and, as a result, the Company does not consolidate TRC in its consolidated financial statements.

TRC is recognized in the Company's consolidated financial statements under the equity method of accounting. Income related to the Company's equity ownership of TRC is reflected within its consolidated statements of operations and is classified as non-operating income.

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are anticipated to be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company's total unrecognized tax benefits of $63.4 million and $58.8 million, as of December 31, 2020 and December 31, 2019, respectively, may reduce the effective tax rate in the period of recognition. The Company currently has a full valuation allowance against its deferred tax assets, which would impact the timing of the effective tax rate benefit should any of the Company's uncertain positions be favorably settled in the future.

The Company assesses all material positions, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than 50% likely to be realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether the factors underlying the sustainability assertion have changed and whether the amount of the recognized tax benefit is still appropriate.

The recognition and measurement of tax benefits requires significant judgment. The Company has taken certain positions where it believes that its position is greater than 50% likely to be realized upon ultimate settlement and for which no reserve for uncertain tax positions has been recorded. If the Company does not ultimately realize the expected benefit of these positions, it will record additional income tax expenses in future periods. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Any tax levied or credited by a governmental taxing authority that is not based on the Company's income is outside the scope of accounting for income taxes. Therefore, the Company records such items as a component of its loss before income taxes.

Net Loss per Share

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

	Year Ended December 31,		
(In thousands, except per share data)	**2020**	**2019**	**2018**
Numerator:			
Net loss	$ (278,017)	$ (236,455)	$ (215,524)
Denominator:			
Weighted-average ordinary shares outstanding	62,808	56,452	55,076
Less: weighted-average ordinary shares subject to forfeiture	(463)	(842)	(1,107)
Weighted-average ordinary shares used to compute basic and diluted net loss per share	62,345	55,610	53,969
Basic and diluted net loss per share	$ (4.46)	$ (4.25)	$ (3.99)

For the year ended December 31, 2020, 2019 and 2018, diluted and basic net loss per share were 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:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Share issuances under equity incentive plans and ESPP	6,553	6,577	3,492
Restricted shares	—	—	2
Share issuances upon the conversion of convertible senior notes	6,676	6,676	6,676
Total	13,229	13,253	10,170

In addition, there were 414,000 and 978,750 shares subject to performance-based vesting criteria which have been excluded from the ordinary equivalent shares table above for the year ended December 31, 2019 and 2018, respectively. There were no such shares excluded as of December 31, 2020.

Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on the Company's available-for-sale investments.

Related Parties

GSK owned 15.0% of the Company's ordinary shares outstanding as of December 31, 2020. On June 22, 2020, GSK Finance (No.3) plc ("GSK Finance"), a wholly-owned subsidiary of GSK, issued $280,336,000 of exchangeable senior notes due 2023 (the "GSK Notes"), initially exchangeable into 9,644,792 ordinary shares of Theravance Biopharma held by GSK and its affiliates. The GSK Notes are guaranteed by GSK and are exchangeable at the option of noteholders on any business day on or after September 1, 2020. The GSK Notes will mature on June 22, 2023 and do not bear interest. The GSK Notes were offered at an issue price 108.5% of their principal amount. The initial exchange rate is 34.4044 shares of Theravance Biopharma ordinary shares per $1,000 principal amount of GSK Notes, which is equivalent to an initial exchange price of approximately $29.066 per share, representing a premium of 35% over the volume weighted-average price of Theravance Biopharma's ordinary shares on June 17, 2020.

Upon exchange of the GSK Notes, GSK Finance is expected to deliver its ordinary shares of Theravance Biopharma, but may at its option under certain circumstances, deliver cash or a combination of Theravance Biopharma ordinary shares and cash to noteholders. The GSK offering involves the expected exchange of substantially all of the 9,644,807 ordinary shares of Theravance Biopharma held by GSK and its affiliates. Theravance Biopharma will not be issuing any new ordinary shares in connection with the GSK offering, and Theravance Biopharma did not receive any proceeds from the GSK offering.

Robert V. Gunderson, Jr. is a member of the Company's board of directors. The Company has engaged Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, of which Mr. Gunderson is a partner, as its primary legal counsel. Fees incurred for services provided by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP were $0.5 million, $0.4 million and $0.5 million for the year ended December 31, 2020, 2019 and 2018, respectively.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on

available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. ASU 2016-13 became effective on January 1, 2020, and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures primarily due to the high credit quality and short-term maturities of the Company's marketable securities.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Accordingly, ASU 2018-15 requires a customer in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 became effective on January 1, 2020, and the adoption did not have a material impact on the Company's consolidated financial statements and related disclosures. However, the adoption of ASU 2018-15 may result in an increase in capitalized assets related to qualifying cloud computing arrangement implementation costs in the future.

In November 2018, the FASB issued ASU 2018-18, *Collaboration Arrangements: Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). The issuance of Topic 606 raised questions about the interaction between the guidance on collaborative arrangements and revenue recognition. ASU 2018-18 addresses this uncertainty by: (i) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaboration arrangement participant is a customer; (ii) adding unit of account guidance to assess whether the collaboration arrangement or a part of the arrangement is with a customer; and (iii) precluding a company from presenting transactions with collaboration arrangement participants that are not directly related to sales to third parties together with revenue from contracts with customers. ASU 2018-18 became effective on January 1, 2020, and the Company elected to adopt ASU 2018-18 retrospectively, only for contracts that were not completed as of January 1, 2020. The adoption of ASU 2018-18 did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12") as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards. ASU 2019-12 removes certain exceptions from Topic 740, *Income Taxes*, including (i) the exception to the incremental approach for intra period tax allocation when there is a loss from continuing operations and income or a gain from other items such as discontinued operations or other comprehensive income; (ii) the exception to accounting for outside basis differences of equity method investments and foreign subsidiaries; and (iii) the exception to limit tax benefit recognized in interim periods in cases when the year-to-date losses exceed anticipated losses. ASU 2019-12 also simplifies GAAP in several other areas of Topic 740 such as (i) franchise taxes and other taxes partially based on income; (ii) step-up in tax basis goodwill considered part of a business combination in which the book goodwill was originally recognized or should be considered a separate transaction; (iii) separate financial statements of entities not subject to tax; and (iv) interim recognition of enactment of tax laws or rate changes. ASU 2019-12 is effective for annual reporting periods and interim periods within those years beginning after December 15, 2020. The adoption of ASU 2019-12 is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging: Contracts in Entity's Own Equity (Subtopic 815-10)* ("ASU 2020-06"). ASU 2020-06 simplifies the complexity associated with applying US GAAP for certain financial instruments with characteristics of liabilities and equity by removing certain accounting models which separate the embedded conversion features from the host contract for convertible instruments. The standard also enhances the consistency of earnings-per-share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings-per-share calculations. ASU 2020-06 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2021, and early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2020-06 on its consolidated financial statements and related disclosures.

The Company has evaluated other recently issued accounting pronouncements and does not currently believe that any of these pronouncements will have a material impact on its consolidated financial statements and related disclosures.

2. Revenue

Revenues from Collaborative Arrangements

The Company recognized revenues from its collaborative arrangements as follows:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Janssen	$ 26,426	$ 31,096	$ 31,053
Alfasigma	14	125	10,678
Other	24	29	60
Total collaboration revenue	$ 26,464	$ 31,250	$ 41,791

Changes in Deferred Revenue Balances

Changes in deferred revenue balances arose as a result of the Company recognizing the following revenue from collaborative arrangements during the periods below:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Collaboration revenue recognized in the period from:			
Amounts included in deferred revenue at the beginning of the period	$ 26,464	$ 31,245	$ 130
Performance obligations satisfied in previous period	—	—	—

Janssen Biotech

In February 2018, the Company entered into a global co-development and commercialization agreement with Janssen Biotech, Inc. (“Janssen”) for izencitinib (formerly known as 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, the Company received an upfront payment of $100.0 million. The Company is conducting a Phase 2 (DIONE) study of izencitinib in Crohn’s disease and a Phase 2b/3 (RHEA) induction and maintenance study of izencitinib in ulcerative colitis. Following the initial Phase 2 development period, including the 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 izencitinib and certain related back-up compounds by paying the Company a fee of $200.0 million. Upon any such election, the Company and Janssen will jointly develop and commercialize izencitinib in inflammatory intestinal diseases and share profits in the US and expenses related to Phase 3 development and registration activities (67% to Janssen; 33% to Theravance Biopharma). The Company would receive royalties on ex-US sales at double-digit tiered percentage royalty rates, and the Company would be eligible to receive up to an additional $700.0 million in development and commercialization milestone payments from Janssen.

The Janssen Agreement is considered to be within the scope of Accounting Standards Codification, Topic 808, *Collaborative Arrangements* (“ASC 808”), as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the Janssen Agreement and determined it is partially within the scope of Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) as the research and development activities to be performed through the initial Phase 2 development period of the collaborative arrangement are considered to be part of the Company’s ordinary activities. The Company has identified research and development activities as its only performance obligation. The Company further determined that the transaction price under the arrangement was the $100.0 million upfront payment which was allocated to the single performance obligation.

The $900.0 million in future potential payments, inclusive of the $200.0 million opt-in fee and $700.0 million future development and commercialization milestones, is considered variable consideration if Janssen elects to remain in the collaboration arrangement following completion of the initial Phase 2 development period, 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 the Company's evaluation of this variable consideration constraint, it determined that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of its control. The Company expects that any consideration related to royalties and sales-based milestones will be recognized when the subsequent sales occur.

For the year ended December 31, 2020, 2019 and 2018, the Company recognized $26.4 million, $31.1 million, and $31.1 million as revenue from collaboration arrangements related to the Janssen Agreement. The remaining transaction price of $11.4 million, related to the $100.0 million upfront payment, was recorded in deferred revenue on the consolidated balance sheets and is expected to be recognized as collaboration revenue as the research and development services are delivered over the initial Phase 2 development period. Collaboration revenue is recognized for the research and development services based on a measure of the Company's efforts toward satisfying the performance obligation relative to the total expected efforts or inputs to satisfy the performance obligation (e.g., costs incurred compared to total budget). Consequently, delays in trial activity and/or changes to the total budget will impact the timing and amount of revenue recognized in any given reporting period. For the year ended December 31, 2020, 2019 and 2018, the Company incurred $38.5 million, $39.9 million and $38.6 million, respectively, in research and development costs related to the Janssen Agreement. In future reporting periods, the Company will reevaluate the estimates related to its efforts towards satisfying the performance obligation and may record a change in estimate if deemed necessary.

Viatris

In January 2015, the Company and Viatris Inc. (formerly, Mylan Ireland Limited) ("Viatris") established a strategic collaboration (the "Viatris Agreement") for the development and commercialization of revefenacin, including YUPELRI® (revefenacin) inhalation solution. The Company entered into the collaboration to expand the breadth of its revefenacin development program and extend its commercial reach beyond the hospital setting.

Under the Viatris Agreement, Viatris paid the Company an upfront fee of $15.0 million for the delivery of the revefenacin license in 2015 and, in 2016, Viatris paid the Company a milestone payment of $15.0 million for the achievement of 50% enrollment in the related Phase 3 twelve-month safety study.

As of December 31, 2020, excluding the aggregate $30.0 million payment noted above, the Company is eligible to receive from Viatris potential global (ex-China and adjacent territories) development, regulatory and sales milestone payments totaling up to $205.0 million in the aggregate, with $160.0 million associated with YUPELRI monotherapy, and $45.0 million associated with 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"). The $45.0 million associated with future potential combination products relates solely to development and regulatory actions.

The Viatris Agreement is considered to be within the scope of ASC 808 and partially within the scope of ASC 606, as the parties are active participants and exposed to the risks and rewards of the collaborative activity with a unit of account provided to Viatris as a customer. Under the terms of the Viatris Agreement, Viatris was responsible for reimbursement of the Company's costs related to the registrational program up until the approval of the first new drug application in November 2018, thereafter, R&D expenses are shared. 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, the Company did not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

The Company determined the license to develop and commercialize revefenacin to be a unit of account and a separate performance obligation for which Viatris is a customer. The joint steering committee participation was also determined to be a performance obligation for which the Company analogized to ASC 606 to recognize revenue. Using the concepts from ASC 606, the Company further determined that the transaction price under the arrangement was comprised of the following: (1) $15.0 million upfront license fee received in 2015; (2) $4.2 million premium received in 2015 related to an ordinary share purchase agreement with Viatris; 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 the Company's best estimate of the relative stand-alone selling prices. For the delivery of the license, the Company 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, the Company based the stand-alone selling price on the average compensation of its committee members estimated to be incurred over the performance period. The Company expects to recognize collaboration revenue from the committee participation ratably over the performance period of approximately seventeen years.

The future potential milestone amounts for the Viatris Agreement were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of the Company's evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

As of December 31, 2020, $0.3 million was recorded in deferred revenue on the consolidated balance sheets related to the Viatris Agreement. This amount reflects revenue allocated to joint steering committee participation which will be recognized as collaboration revenue over the course of the remaining performance period of approximately eleven years.

The Company is also entitled to a share of US profits and losses (65% to Viatris; 35% to Theravance Biopharma) received in connection with commercialization of YUPELRI, and the Company is entitled to low double-digit tiered royalties on ex-US net sales. Viatris is the principal in the sales transactions, and as a result, the Company does not reflect the product sales in its consolidated financial statements.

Following the US Food and Drug Administration ("FDA") approval of YUPELRI in November 2018, net amounts payable to or receivable from Viatris each quarter under the profit-sharing structure are disaggregated according to their individual components. In accordance with the applicable accounting guidance, amounts receivable from Viatris in connection with the commercialization of YUPELRI are recorded within the consolidated statements of operations as revenue from "Viatris collaboration agreement" irrespective of whether the overall collaboration is profitable. Amounts payable to Viatris in connection with the commercialization of YUPELRI are recorded within the consolidated statements of operations as a collaboration loss within selling, general and administrative expenses. Any reimbursement from Viatris attributed to the 65% cost-sharing of the Company's R&D expenses is characterized as a reduction of R&D expense, as the Company does not consider performing research and development services for reimbursement to be a part of its ordinary activities.

The following YUPELRI-related amounts were recognized within revenue and selling, general and administrative expense in the Company's consolidated statements of operations:

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
Viatris collaboration agreement - *Amounts receivable from Viatris*	$ 43,893	$ 13,664	$ 3,275
Collaboration loss - *Amounts payable to Viatris*	$ —	$ 1,582	$ 2,997

Prior to the FDA approval of YUPELRI in late 2018, the Company recognized its 35% share of expenses within R&D expense and selling, general and administrative expense on its consolidated statements of operations.

While Viatris records the total net sales of YUPELRI within its consolidated financial statements, Viatris collaboration agreement revenue includes the Company's implied 35% share of net sales of YUPELRI for the year ended December 31, 2020, 2019, and 2018 of $50.0 million, $19.3 million, $3.7 million, respectively.

Alfasigma

Under an October 2012 development and collaboration agreement for velusetrag, the Company 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 the Company retained full rights to velusetrag in the US, Canada, Japan and certain other countries.

In April 2018, Alfasigma exercised its exclusive option to develop and commercialize velusetrag, and the Company elected not to pursue further development of velusetrag. As a result, the Company is transferring global rights for velusetrag to Alfasigma under the terms of the existing collaboration agreement. The Company received a $10.0 million option exercise fee and a $1.0 million non-refundable reimbursement from Alfasigma, and the Company is eligible to receive future potential development, regulatory and sales milestone payments of up to $26.8 million and tiered royalties on global net sales ranging from high single digits to the mid-teens.

The Alfasigma Agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company has historically received reimbursements related to R&D services performed under the Alfasigma Agreement. Performing R&D services for reimbursement is considered to be a collaborative activity under the scope of ASC 808. Reimbursable program costs are accounted for as reductions to R&D expense. For this unit of account, the Company does not recognize revenue or analogize to ASC 606 and, as such, the reimbursable program costs are excluded from the transaction price.

As a result of Alfasigma's election to exercise its exclusive option to develop and commercialize velusetrag in April 2018, Alfasigma paid the Company a total of $11.0 million, comprised of the $10.0 million option exercise fee and the $1.0 million non-refundable reimbursement. The Company analogized to ASC 606 for the delivery of the following identified performance obligations: (i) delivery of the velusetrag license; (ii) transfer of technical know-how; (iii) delivery of clinical study reports ("CSRs"); (iv) delivery of registration batches, including drug substances; and (v) joint steering committee participation. The Company determined that all of the five performance obligations were distinct, and it allocated the transaction price based on the estimated stand-alone selling prices of each of the performance obligations. The stand-alone selling price of the license was based 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.

The Company determined that any potential development or regulatory milestones were to be fully constrained as prescribed under ASC 606. As part of its evaluation of this variable consideration constraint, the Company determined that the potential payments are contingent upon developmental and regulatory milestones that are uncertain and are highly susceptible to factors outside of the Company's control. In addition, the Company expects that any consideration related to sales-based milestones would be recognized when the subsequent sales occur.

For the year ended December 31, 2019, and 2018, the Company recognized $0.1 million and $10.7 million, respectively, as revenue from collaboration arrangements related to the Alfasigma Agreement. There was a minimal amount of collaboration revenue recognized related to the Alfasigma Agreement for the year ended December 31, 2020, and as of December 31, 2020, $0.2 million remains in deferred revenue on the consolidated balance sheets and is expected to be recognized as collaboration revenue over approximately the next six years.

Reimbursement of R&D Expenses

As noted above, under certain collaborative arrangements the Company is entitled to reimbursement of certain R&D expenses. Activities under collaborative arrangements for which the Company is entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, the Company does not

analogize to ASC 606 or recognize revenue. The Company records reimbursement payments received from its collaboration partners as reductions to R&D expense.

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

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Janssen	$ 8,554	$ 5,129	$ 1,597
Viatris	1,524	460	7,515
Total reduction to R&D expense, net	$ 10,078	$ 5,589	$ 9,112

Revenue from Licensing Arrangements

Viatris

In June 2019, the Company announced the expansion of the Viatris Agreement (the "Viatris Amendment") to grant Viatris exclusive development and commercialization rights to nebulized revefenacin in China and adjacent territories. In exchange, the Company received an upfront payment of $18.5 million (before a required tax withholding) and will be eligible to receive potential development and sales milestones totaling $54.0 million and low double-digit tiered royalties on net sales of nebulized revefenacin, if approved. Of the $54.0 million in potential milestones, $9.0 million is associated with the development of YUPELRI monotherapy, $7.5 million associated with the development of future potential combination products, and $37.5 million is associated with sales milestones. Viatris is responsible for all aspects of development and commercialization in the partnered regions, including pre- and post-launch activities and product registration and all associated costs.

The Viatris Amendment is accounted for under ASC 606 as a separate contract from the original Viatris Agreement that was entered into in January 2015. The Company identified a single performance obligation comprising of the delivery of the license to develop and commercialize revefenacin in China and adjacent territories. The transaction price was determined to be the upfront payment of $18.5 million which the Company recognized as licensing revenue following the completion of the performance obligation in June 2019.

The future potential milestone amounts for the Viatris Amendment were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of the Company's evaluation of the development milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

In March 2020, the Company earned a $1.5 million development milestone payment for the acceptance of a clinical trial application associated with the use of YUPELRI monotherapy in China and adjacent territories.

Pfizer

In December 2019, the Company entered into a global license agreement with Pfizer Inc. for its preclinical skin-selective, locally-acting pan-JAK inhibitor program (the "Pfizer Agreement"). The compounds in this program are designed to target validated pro-inflammatory pathways and are specifically designed to possess skin-selective activity with minimal systemic exposure.

Under the Pfizer Agreement, Pfizer has an exclusive license to develop, manufacture and commercialize certain compounds for all uses other than gastrointestinal, ophthalmic and respiratory applications. Under the terms of the Pfizer Agreement, the Company received an upfront cash payment of $10.0 million and is eligible to receive up to an additional $240.0 million in development and sales milestone payments from Pfizer. In addition, the Company will be eligible to receive a tiered royalty on worldwide net sales of any potential products under the license at percentage royalty rates ranging from middle single-digits to low double-digits.

The Pfizer Agreement is accounted for under ASC 606. The Company identified two performance obligations primarily comprised of the delivery of the license and samples of tangible materials which was completed in December 2019. The transaction price was determined to be the upfront payment of $10.0 million which the Company recognized as licensing revenue in December 2019.

The future potential milestones payable under the Pfizer Amendment were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of the Company's evaluation of the development milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. The Company expects that the sales-based milestone payments will be recognized when the sales occur or the milestone is achieved. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur.

3. Sale of VIBATIV

On November 12, 2018, the Company completed the sale of its assets related to the manufacture, marketing and sale of VIBATIV to Cumberland pursuant to the Asset Purchase Agreement dated November 1, 2018 (the "APA"). Under the APA, Cumberland paid the Company $20.0 million at the closing of the transaction and $5.0 million in April 2019. In addition, Cumberland pays the Company tiered royalties of up to 20% of US net sales of VIBATIV until such time as royalties cumulatively total $100.0 million.

In connection with the closing of the transaction, Cumberland acquired, among other things, (i) intellectual property rights relating to VIBATIV; (ii) active pharmaceutical ingredient for VIBATIV, work-in-process and finished drug product; (iii) the US marketing authorization for VIBATIV; (iv) certain assigned contracts relating to the manufacture and commercialization of VIBATIV; and (v) books and records related to VIBATIV. Cumberland also assumed certain clinical study obligations related to VIBATIV and certain post-closing liabilities and obligations as described in the APA.

The Company retained financial responsibility for any liabilities relating to products sold prior to the closing of the transaction, and Cumberland assumed financial responsibility for any liabilities relating to products sold on or after the closing of the transaction. The Company agreed to provide transition services to Cumberland for limited periods of time following the closing of the transaction. The Company has also agreed for a limited period not to engage in specified activities that would compete with the manufacture, marketing and sale of VIBATIV.

The Company recognized a net gain of $6.1 million upon the sale of VIBATIV within "Interest and other income, net" in the consolidated statements of operations for the year ended December 31, 2018. Transition-related costs of $1.1 million were recognized concurrently and included as a reduction to the net gain on the sale. The Company records the royalties receivable from US net sales by Cumberland within the same "Interest and other income, net".

4. Segment Information

The Company operates in a single segment, which is the discovery (research), development and commercialization of human therapeutics. The following table summarizes total revenue by geographic region:

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
US	$ 70,319	$ 54,760	$ 49,239
Europe	1,538	18,654	11,117
Asia	—	—	14
Total revenue	$ 71,857	$ 73,414	$ 60,370

The following table summarizes total revenue from each of the Company's customers or collaboration partners who individually accounted for 10% or more of total revenue (as a percentage of total revenues) during the most recent three years:

	Year Ended December 31,		
(% of total revenue)	2020	2019	2018
Viatris	63 %	44 %	—
Janssen	37 %	42 %	51 %
Pfizer	—	14 %	—
Alfasigma	—	—	18 %

5. Cash, Cash Equivalents, and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the current period and comparable prior year period consolidated balance sheets that sum to the total of the same such amounts shown on the consolidated statements of cash flows.

	December 31,		
(In thousands)	2020	2019	2018
Cash and cash equivalents	$ 81,467	$ 58,064	$ 378,021
Restricted cash	833	833	833
Total cash, cash equivalents, and restricted cash shown on the consolidated statements of cash flows	$ 82,300	$ 58,897	$ 378,854

The Company maintains restricted cash for certain lease agreements and letters of credit by which the Company has pledged cash and cash equivalents as collateral. As of December 31, 2020, the Company also maintained restricted cash for debt servicing of its 9.5% non-recourse 2035 notes. See *"Note 7. Debt"* for further information regarding the 9.5% non-recourse 2035 notes. The cash-related amounts reported in the table above exclude the Company's investments in short and long-term marketable securities that are reported separately on the consolidated balance sheets.

6. 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 obtained from a commercial pricing service. The fair market value of marketable securities classified within Level 1 is based on quoted prices for identical instruments in active markets. The fair value of marketable securities classified within Level 2 is based on quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; or model-driven valuations whose inputs are observable or whose significant value drivers are observable. Observable inputs 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:

		December 31, 2020			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	$ 75,036	$ 34	$ —	$ 75,070
US government agency securities	Level 2	74,971	18	—	74,989
Corporate notes	Level 2	5,046	—	(1)	5,045
Commercial paper	Level 2	56,374	1	(5)	56,370
Marketable securities		211,427	53	(6)	211,474
Money market funds	Level 1	—	—	—	—
Total		$ 211,427	$ 53	$ (6)	$ 211,474

		December 31, 2019			
(In thousands)		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
US government securities	Level 1	$ 100,746	$ 108	$ —	$ 100,854
Corporate notes	Level 2	25,466	9	(1)	25,474
Commercial paper	Level 2	112,066	31	(2)	112,095
Marketable securities		238,278	148	(3)	238,423
Money market funds	Level 1	35,736	—	—	35,736
Total		$ 274,014	$ 148	$ (3)	$ 274,159

As of December 31, 2020, all of the Company's available-for-sale securities had contractual maturities within 8 months and the weighted-average maturity of marketable securities was approximately 3 months. There were no transfers between Level 1 and Level 2 during the periods presented, and there have been no material changes to the Company's valuation techniques during the year ended December 31, 2020 or 2019.

Available-for-sale debt securities with unrealized losses are summarized below:

	December 31, 2020					
	Less than 12 Months		Greater than 12 Months		Total	
(In thousands)	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate notes	$ 5,045	$ (1)	$ —	$ —	$ 5,045	$ (1)
Commercial paper	39,375	(5)	—	—	39,375	(5)
Total	$ 44,420	$ (6)	$ —	$ —	$ 44,420	$ (6)

	December 31, 2019					
	Less than 12 Months		Greater than 12 Months		Total	
(In thousands)	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate notes	$ 5,507	$ (1)	$ —	$ —	$ 5,507	$ (1)
Commercial paper	28,137	(2)	—	—	28,137	(2)
Total	$ 33,644	$ (3)	$ —	$ —	$ 33,644	$ (3)

The Company invests primarily in high credit quality and short-term maturity debt securities with the intent to hold such securities until maturity at par value. The Company does not intend to sell the investments that are currently in an unrealized loss position, and it is unlikely that it will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company reviewed its available-for-sale debt securities and determined that there were no credit-related losses to be recognized as of December 31, 2020.

As of December 31, 2020, the Company's accumulated other comprehensive income on its consolidated balance sheets consisted of net unrealized gains or losses on available-for-sale investments. For the year ended December 31, 2020, the Company sold marketable securities for total proceeds of $19.9 million and recognized minimal net realized gains from the sales based on the specific identification method. For the year ended December 31, 2019 and 2018, the Company did not sell any of its marketable securities.

7. Debt

Debt consisted of the following liability components:

	December 31,	
(In thousands)	2020	2019
9.5% Non-Recourse 2035 Notes:		
Principal amount	$ 418,572	$ —
Less: 5% retained by the Company	(20,929)	—
Unamortized debt issuance costs - 9.5% Non-Recourse 2035 Notes	(3,847)	—
Unamortized debt issuance costs - Modified 9.0% Non-Recourse 2033 Notes	(1,589)	—
3.25% Convertible 2023 Notes:		
Principal amount	230,000	230,000
Unamortized debt issuance costs	(3,037)	(4,110)
9.0% Non-Recourse 2033 Notes:		
Principal amount	—	247,734
Less: 5% retained by the Company	—	(12,387)
Unamortized debt issuance costs	—	(6,196)
Total debt	$ 619,170	$ 455,041

Debt interest expense consists of the following components:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Stated coupon interest	$ 42,625	$ 28,811	$ 9,316
Amortization of debt issuance costs	1,960	3,051	1,166
Total debt interest expense	$ 44,585	$ 31,862	$ 10,482

9.5% Non-Recourse Notes Due 2035

On February 21, 2020, Theravance Biopharma R&D, Inc. ("Theravance R&D"), a wholly-owned subsidiary of the Company, and Triple Royalty Sub II LLC (the "Issuer II" or "Triple II"), a wholly-owned subsidiary of Theravance Biopharma R&D, entered into certain note purchase agreements ("Note Purchase Agreements") with certain note purchasers ("Note Purchasers"), relating to the private placement by Issuer II of $400.0 million 9.5% Fixed Rate Term Notes due on or before 2035 (the "Non-Recourse 2035 Notes"). Ninety-five percent of the Non-Recourse 2035 Notes were sold to the Note Purchasers pursuant to the Note Purchase Agreements. The remaining 5% of the Non-Recourse 2035 Notes (the "Retained Notes") were retained by the Company to comply with Regulation RR — Credit Risk Retention (17 C.F.R. Part 246). The Retained Notes are eliminated in the Company's consolidated financial statements. The transaction closed on February 28, 2020.

The Non-Recourse 2035 Notes are secured by all of Issuer II's right, title and interest as a holder of certain membership interests (the "Issuer II Class C Units") in Theravance Respiratory Company, LLC ("TRC"). TRC holds the right to receive upward-tiering royalties ranging from 6.5% to 10% on worldwide net sales of TRELEGY, and the Company holds an 85% economic interest in TRC. The Issuer II Class C Units represent 75% of the Company's 85% economic interest, which equates to 63.75% of the economic interests in TRC.

The source of principal and interest payments for the Non-Recourse 2035 Notes are the future royalty payments generated from the TRELEGY program, and as a result, the holders of the Non-Recourse 2035 Notes have no recourse against the Company even if the TRELEGY payments are insufficient to cover the principal and interest payments for

the Non-Recourse 2035 Notes. Prior to and including the December 5, 2024 payment date, in the event that the distributions received by the Issuer II from TRC in a quarter is less than the interest accrued for that quarter, the principal amount of the Non-Recourse 2035 Notes will increase by the interest shortfall amount for that quarter. The net principal amount of the Non-Recourse 2035 Notes increased by $17.6 million which represented the shortfall between the distributions received from TRC and the total interest payments due during the year ended December 31, 2020. While the holders of the Non-Recourse 2035 Notes have no recourse against the Company, the terms of the Non-Recourse 2035 Notes also provide that the Company, at its option, may satisfy the quarterly interest payment obligations by making a capital contribution to the Issuer II.

The Non-Recourse 2035 Notes are not convertible into Company equity and have no security interest in nor rights under any agreement with Glaxo Group Limited or one of its affiliates ("GSK"). See *"Note 9. Theravance Respiratory Company, LLC"* for further information regarding GSK. The Non-Recourse 2035 Notes may be redeemed by Issuer II on and after February 28, 2022, in whole or in part, at specified redemption premiums. The Non-Recourse 2035 Notes bear an annual interest rate of 9.5%, with interest and principal paid quarterly beginning June 5, 2020. Since the principal and interest payments on the Non-Recourse 2035 Notes are ultimately based on royalties from TRELEGY product sales, which will vary from quarter to quarter, the Non-Recourse 2035 Notes may be repaid prior to the final maturity date in 2035. Following the redemption or repayment of the Non-Recourse 2035 Notes, all TRELEGY-related pledged cash flows will revert back to the Company.

The portion of the Non-Recourse 2035 Notes classified as a current liability, if any, is based on the amount of royalties received, or receivable, as of December 31, 2020, that are expected to be used to make a principal repayment on the Non-Recourse 2035 Notes within the next 12 months.

As of December 31, 2020, the net principal and estimated fair value of the Non-Recourse 2035 Notes were $397.6 million and $399.6 million, respectively. The inputs to determine fair value of the Non-Recourse 2035 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.

9.0% Non-Recourse Notes Due 2033

In November 2018, the Company entered into note purchase agreements relating to the private placement of $250.0 million aggregate principal amount of 9.0% non-recourse notes, due on or before 2033 (the "Non-Recourse 2033 Notes") issued by the Company's wholly-owned subsidiary, Triple Royalty Sub LLC (the "Issuer"). On February 28, 2020, the Company refinanced the Non-Recourse 2033 Notes by issuing the Non-Recourse 2035 Notes and a portion of those proceeds were used to repay, in full, the remaining outstanding balance of the Company's Non-Recourse 2033 Notes. Pursuant to the terms of the Non-Recourse 2033 Notes, the Company paid a debt redemption premium of 5% of the outstanding principal as of the refinancing date.

The refinancing of the Non-Recourse 2033 Notes involved multiple lenders who were considered members of a loan syndicate. To determine whether the refinancing was to be accounted for as a debt extinguishment or modification, the Company considered whether the lenders involved in the Non-Recourse 2033 Notes and the Non-Recourse 2035 Notes remained the same or changed and whether the change in debt terms was substantial. The debt terms are considered substantially different if the present value of the cash inflows and outflows of the Non-Recourse 2035 Notes, including all principal increases and lender fees on the refinancing date, was at least 10% different from the present value of the remaining cash inflows and outflows of the Non-Recourse 2033 Notes (the "10% Test"). The Company performed the 10% Test for each individual lender participating in the loan syndication by assuming the exercise and non-exercise of the prepayment option. The cash flow assumption generating the smaller change was used as the basis for determining whether the 10% threshold was met. For existing lenders who participated in the Non-Recourse 2035 Notes as part of the new loan syndicate, the refinancing was accounted for as an extinguishment or a modification depending upon whether the change in the cash flows was more or less than 10%, respectively. Amounts due to lenders of the Non-Recourse 2033 Note offering who did not participate in the Non-Recourse 2035 Notes were accounted for as a debt extinguishment.

For debt determined to be extinguished, the total unamortized deferred financing costs and the associated redemption premium of $15.5 million were expensed as “Loss on extinguishment of debt” within the consolidated statements of operations for the year ended December 31, 2020. In addition, $0.3 million of new third-party costs were expensed, and $4.4 million of new creditor fees were capitalized as debt discount. For debt determined to be modified, $0.5 million of new creditor fees were expensed, and the related unamortized deferred financing costs of $1.8 million, as of February 28, 2020, will continue to be amortized through the remaining term of the Non-Recourse 2035 Notes.

3.25% Convertible Senior Notes Due 2023

In November 2016, the Company completed an underwritten public offering of $230.0 million of 3.25% convertible senior notes, due 2023 (the "Convertible Senior 2023 Notes") for net proceeds of $222.5 million. The Company incurred $7.5 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the Convertible Senior 2023 Notes. The Convertible Senior 2023 Notes bear an annual interest rate of 3.25%, payable semi-annually in arrears, on November 1 and May 1 of each year.

The Convertible Senior 2023 Notes are senior unsecured obligations and rank senior in right of payment to any of the Company’s indebtedness that is expressly subordinated in right of payment to the Convertible Senior 2023 Notes; equal in right of payment to any of the Company’s indebtedness that is not so subordinated; effectively junior in right of payment to any of the Company’s secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of the Company’s subsidiaries.

The Convertible Senior 2023 Notes will mature on November 1, 2023, unless earlier redeemed or repurchased by the Company or converted. Holders may convert their Convertible Senior 2023 Notes into ordinary shares at an initial conversion rate of 29.0276 shares for each $1,000 principal amount of Convertible Senior 2023 Notes, which is equivalent to an initial conversion price of approximately $34.45 per share, subject to adjustment, in certain circumstances (including upon the occurrence of a fundamental change), at any time prior to the close of business on the second business day immediately preceding the maturity date. Upon the occurrence of a fundamental change involving the Company, holders of the Convertible Senior 2023 Notes may require the Company to repurchase all or a portion of their Convertible Senior 2023 Notes for cash at a redemption price equal to 100% of the principal amount of the Convertible Senior 2023 Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, in some circumstances, the conversion rate of the Convertible Senior 2023 Notes will increase with a make whole premium for conversions in connection with certain fundamental changes.

The debt issuance costs related to the Convertible Senior 2023 Notes offering were capitalized as deferred financing costs and presented as a reduction of the carrying value of the financial liability on the Company’s consolidated balance sheets at December 31, 2020 and 2019.

The estimated fair value of the Convertible Senior 2023 Notes was $217.9 million and $236.0 million at December 31, 2020 and 2019, respectively. The estimated fair value was primarily based upon the underlying price of Theravance Biopharma’s publicly traded shares and other observable inputs as of December 31, 2020 and 2019. The inputs to determine fair value of the Convertible Senior 2023 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.

8. Leases

The Company leases approximately 170,000 square feet of office and laboratory space in two buildings in South San Francisco, California, under a non-cancelable operating lease that ends in May 2030 (“SSF Lease”). This lease includes a tenant improvement allowance that expires in May 2022 and had a remaining balance of $12.1 million and $15.6 million, as of December 31, 2020 and 2019, respectively. The Company’s Irish subsidiary leases approximately 6,100 square feet of office space in Dublin, Ireland under a lease that expires in April 2027 (“Dublin

Lease"). In addition, the Company leases equipment for clinical research studies with an estimated lease term ending in August 2022.

The SSF Lease contains two options to extend the term of the lease for successive periods of five years each, and the Dublin Lease contains a lease termination option in April 2024 at the Company's discretion. The equipment lease has undergone extensions to the initial lease term due to delays in patient enrollment in the clinical trial, which the Company has characterized as lease modifications. The equipment lease contains options to terminate the agreements at the Company's discretion. The two options to extend the SSF Lease and the options to terminate the Dublin Lease and equipment lease were not recognized in the determination of the Company's right-of-use assets and lease liabilities below.

The Company has evaluated its leases and determined that they were all operating leases. The present values of the remaining lease payments and corresponding right-of-use assets were as follows, and the difference between the right-of-use assets and lease liabilities was due to office-related deferred rent payments that are payable in future periods.

(In thousands)	Classification	December 31, 2020	December 31, 2019
Assets			
Operating lease assets	Operating lease assets	$ 43,260	$ 46,604
Liabilities			
Current:			
Operating lease liabilities	Operating lease liabilities	$ 9,867	$ 7,762
Non-current:			
Operating lease liabilities	Long-term operating lease liabilities	47,220	47,725
Total operating lease liabilities		$ 57,087	$ 55,487

Lease expense was included within operating expenses in the consolidated statements of operations as follows:

(In thousands)	Classification	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Operating lease expense	Selling, general and administrative expense	$ 7,974	$ 7,959	$ 7,985
Operating lease expense	Research and development expense	758	164	—
Total operating lease expense (1)		$ 8,732	$ 8,123	$ 7,985

(1) Excludes short-term leases which were immaterial and office lease service-related charges.

Cash paid for amounts included in the measurement of lease liabilities was as follows:

(In thousands)	Year Ended December 31, 2020	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 3,804	$ 7,210

As of December 31, 2020, the maturities of the Company's lease liabilities were as follows:

(In thousands)		
Year ending December 31:		
2021	$	10,330
2022		10,345
2023		10,134
2024		10,351
2025		10,649
Thereafter		49,309
Total operating lease payments	$	101,118
Less: Estimated tenant improvement allowance		(12,053)
Less: Imputed interest		(31,978)
Present value of operating lease liabilities	$	57,087

As of December 31, 2020, the weighted-average remaining lease term was 9.1 years, and the weighted-average discount rate used to determine the lease liabilities was 8.64%. The Company's discount rate was primarily derived from the 9.0% interest rate on its previously issued Non-Recourse 2033 Notes in November 2018 and did not involve any significant assumptions.

9. Theravance Respiratory Company, LLC

Through the Company's 85% equity interest in TRC, the Company is 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 (net of TRC expenses paid and the amount of cash, if any, expected to be used by TRC pursuant to the TRC LLC Agreement over the next four fiscal quarters). The primary drug program assigned to TRC is TRELEGY.

In May 2014, the Company entered into the TRC LLC Agreement with Innoviva, Inc. ("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. The Company is responsible for its proportionate share of TRC's administrative expenses incurred, and communicated to the Company, by Innoviva.

The Company analyzed its ownership, contractual and other interests in TRC to determine if it is a variable-interest entity ("VIE"), whether the Company has a variable interest in TRC and the nature and extent of that interest. The Company 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, the Company also assessed whether it is the primary beneficiary of TRC based on the power to direct TRC's activities that most significantly impact TRC's economic performance and its obligation to absorb TRC's losses or the right to receive benefits from TRC that could potentially be significant to TRC. Based on the Company's assessment, the Company determined that it is not the primary beneficiary of TRC, and, as a result, the Company does not consolidate TRC in its consolidated financial statements. TRC is recognized in the Company's consolidated financial statements under the equity method of accounting.

For the year ended December 31, 2020, 2019, and 2018, the Company recognized net royalty income of $68.4 million, $33.7 million, and $11.2 million, respectively, within the consolidated statements of operations within "Income from investment in TRC, LLC". These amounts were recorded net of the Company's share of TRC's expenses of $2.2 million, $2.7 million for the year ended December 31, 2020 and 2019, respectively. There were minimal TRC expenses for the year ended December 31, 2018. The Company's share of TRC expenses for 2020 and 2019 was primarily comprised of TRC legal and related fees associated with the arbitration between Innoviva, TRC and the Company.

As of December 31, 2020, the amounts due from TRC were $53.8 million which were primarily comprised of (i) net royalty income payments for the period from the first quarter of 2020 through the fourth quarter of 2020 and (ii) $8.5 million representing the Company's share of the one-time fee that GSK paid to TRC upon termination of the inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist ("MABA") program in June 2020. The total amounts due, as of December 31, 2020, were net of a $2.5 million payment received from Innoviva in the fourth quarter of 2020 and have been recorded as a current asset in the consolidated balance sheets within "Amounts due from TRC, LLC". In January 2021, the Company received an additional $21.3 million payment from Innoviva related to the receivable balance as of December 31, 2020.

TRC's summary financial information was as follows as of or for the year ended December 31:

(In thousands)	2020	2019	2018
Current assets	$ 63,027	$ 36,737	
Non-current assets	16,959	—	
Current liabilities	508	3,069	
Royalty revenue for the year ended	73,089	42,790	$ 13,379
Revenue from collaborative arrangements for the year ended	10,000	—	—
Income from continuing operations and net income for the year ended	$ 81,662	$ 39,653	$ 13,261

On June 10, 2020, the Company disclosed in a Form 8-K that it had formally objected to TRC and Innoviva, as the manager of TRC, regarding their proposed plan to use TRELEGY royalties to invest in certain privately-held companies, funds that would otherwise be available for distribution to the Company under the terms of the TRC LLC Agreement. In October 2020, Innoviva announced that TRC had invested $15.0 million of TRELEGY royalties in the equity securities of a privately held biopharmaceutical company. Consequently, the Company's share of this investment of $12.8 million has been recorded as a long-term asset in the consolidated balance sheets under "Equity in net assets of TRC, LLC". However, in October 2020, the Company initiated an arbitration proceeding against Innoviva and TRC challenging the authority of Innoviva and TRC to pursue such a business plan rather than distribute such funds to the Company in a manner consistent with the TRC LLC Agreement and the Company's 85% economic interest in TRC. The arbitration hearing was held during the week of February 16, 2021, with post-hearing briefing and arguments to take place over the next few weeks. The Company currently anticipates a decision in those proceedings near the end of the first quarter or early in the second quarter of 2021.

10. Property and Equipment

Property and equipment are held predominantly in the US and consisted of the following:

	December 31,	
(In thousands)	2020	2019
Computer equipment	$ 2,314	$ 2,119
Software	2,076	1,718
Furniture and fixtures	3,812	3,665
Laboratory equipment	29,753	30,546
Leasehold improvements	24,275	22,164
Subtotal	62,230	60,212
Less: accumulated depreciation	(45,808)	(47,568)
Property and equipment, net	$ 16,422	$ 12,644

For the year ended December 31, 2020, 2019 and 2018, depreciation expense for property and equipment was $3.3 million, $3.3 million and $3.0 million, respectively.

11. Share-Based Compensation

Theravance Biopharma Equity Plans

The Company has three equity compensation plans — its 2013 Equity Incentive Plan (the "2013 EIP"), its 2013 Employee Share Purchase Plan (the "2013 ESPP") and its 2014 New Employee Equity Incentive Plan (the "2014 NEEIP"). At inception, the Company was authorized to issue 5,428,571 ordinary shares under the 2013 EIP, 857,142 ordinary shares under the 2013 ESPP, and 750,000 ordinary shares under the 2014 NEEIP.

The 2013 EIP provides for the issuance of share-based awards, including restricted shares, restricted share units, options, share appreciation rights ("SARs") and other equity-based awards, to Company employees, officers, directors and consultants. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2023, the aggregate number of ordinary shares that may be issued under the 2013 EIP shall automatically increase by a number equal to the least of 5% of the total number of ordinary shares outstanding on December 31 of the prior year, 3,428,571 ordinary shares, or a number of ordinary shares determined by the Company's board of directors. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of the Company's 2013 EIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. The Company may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Under the 2013 ESPP, the Company's officers and employees may purchase ordinary shares through payroll deductions at a price equal to 85% of the lower of the fair market value of the ordinary share at the beginning of the offering period or at the end of each applicable purchase period. As of January 1 of each year, commencing on January 1, 2015 and ending on (and including) January 1, 2033, the aggregate number of ordinary shares that may be issued under the 2013 ESPP shall automatically increase by a number equal to the least of 1% of the total number of ordinary shares outstanding on December 31 of the prior year, 571,428 ordinary shares or a number of ordinary shares determined by the Company's board of directors. The ESPP generally provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period generally composed of four consecutive six-month purchase periods. The purchase periods end on either May 15 or November 15. ESPP contributions are limited to a maximum of 15% of an employee's eligible compensation. The 2013 ESPP also includes a feature that provides for the existing offering period to terminate and for participants in that offering period to automatically be enrolled in a new offering period when the fair market value of an ordinary share at the beginning of a subsequent offering period falls below the fair market value of an ordinary share on the first day of such offering period.

The 2014 NEEIP provides for the issuance of share-based awards, including restricted shares, restricted share units, non-qualified options and SARs, to the Company's employees. Options may be granted with an exercise price not less than the fair market value of the ordinary shares on the grant date. Under the terms of the 2014 NEEIP, options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. The Company may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will generally be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Innoviva's Equity Plans

Prior to the spin-off from its former parent company, Innoviva, in 2014 ("Spin-Off"), the Company's employees may have received Innoviva stock-based compensation awards, and, therefore, the following disclosures include information regarding stock-based compensation expense allocated to Theravance Biopharma that relates to Innoviva stock-based equity awards.

At the time of the Spin-Off, Innoviva had one active stock-based incentive plan under which it granted stock-based awards to employees, officers and consultants, the 2012 Equity Incentive Plan. All outstanding stock options and restricted stock units ("RSUs") held by (i) Innoviva employees who became the Company's employees; and (ii) members of the board of directors of Innoviva who became members of the Company's board of directors, in

connection with the Spin-Off were adjusted for the Spin-Off. Such awards, along with outstanding restricted stock awards ("RSAs") held by Innoviva employees who became the Company's employees in connection with the Spin-Off, will continue to vest and remain outstanding based on continuing employment or service with the Company.

The 2012 Equity Incentive Plan provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, stock unit awards and SARs to employees, non-employee directors and consultants. Stock options were granted with an exercise price not less than the fair market value of the common stock on the grant date. Stock options granted to employees generally have a maximum term of 10 years and vest over a four-year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. However, Innoviva granted options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Performance-Contingent Awards

In 2016, the Compensation Committee of the Company's board of directors ("Compensation Committee") approved the grant of 1,575,000 performance-contingent restricted share awards ("RSAs") and 135,000 performance-contingent restricted share units ("RSUs") to senior management. The vesting of such awards is dependent on the Company meeting its critical operating goals and objectives during the five-year period from 2016 to December 31, 2020, as well as, continued employment. 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 should increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment.

Expense associated with these awards may be recognized during the years 2016 to 2020 depending on the probability of meeting certain 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. Previously recognized expense is reversed in the period in which it becomes probable that the requisite service period will not be rendered. The awards are broken into three separate tranches and comprised of a share-based award component and a cash bonus award component. See *"Note 13. Commitments and Contingencies"* for information related to the cash bonus award component.

As of December 31, 2020, there were 414,000 of these performance-contingent RSAs and 54,000 of these performance-contingent RSUs outstanding, and as of December 31, 2019, there were 776,250 of these performance-contingent RSAs and 101,250 of these performance-contingent RSUs outstanding. The performance conditions associated with the first tranche of these awards were completed in the second quarter of 2018, and the Company recognized $1.7 million of share-based compensation expense for the year ended December 31, 2018 associated with the first tranche of these awards.

The performance conditions associated with the second tranche of these awards were completed in the first quarter of 2019, and the expense associated with this second tranche was fully recognized in the first quarter of 2020. For the year ended December 31, 2020, 2019 and 2018, the Company recognized $0.4 million, $1.9 million and $2.6 million, respectively, of share-based compensation expense related to the second tranche of these awards.

In the first quarter of 2020, the performance conditions associated with the remaining third tranche were completed and, as a result, the Company recognized $2.6 million in share-based compensation expense related to these awards for the year ended December 31, 2020. As of December 31, 2020, the maximum remaining expense associated with the third tranche was $0.4 million (allocated as $0.1 million for research and development expense and $0.3 million for selling, general and administrative expense) and will be amortized through the first quarter of 2021.

Separate from the performance-contingent awards described above, the Company periodically grants performance-contingent RSUs to individual employees. For the year ended December 31, 2020 and 2019, the Company recognized $1.0 million of share-based compensation expense related to such awards in each year. As of December 31, 2020, there were 70,000 shares of these performance-contingent RSUs outstanding that have a maximum remaining share-based compensation expense of $0.5 million with performance expiration dates through June 2022.

Share-Based Compensation Expense

Share-based compensation expense included in the consolidated statements of operations was recognized as follows:

(In thousands)	Year Ended December 31, 2020	2019	2018
Research and development	$ 31,294	$ 28,953	$ 25,563
Selling, general and administrative	31,682	31,497	25,750
Total share-based compensation expense	$ 62,976	$ 60,450	$ 51,313

Share-based compensation expense included in the consolidated statements of operations by award type was as follows:

(In thousands)	Year Ended December 31, 2020	2019	2018
Innoviva equity:			
Options	$ —	$ —	$ 280
RSUs	—	—	—
RSAs	—	64	457
Performance RSAs	—	—	—
Theravance Biopharma equity:			
Options	6,536	6,381	8,441
RSUs	49,803	39,520	34,077
Performance RSAs and RSUs	3,943	12,717	4,707
ESPP	2,694	1,768	3,351
Total share-based compensation expense	$ 62,976	$ 60,450	$ 51,313

Total share-based compensation expense capitalized to inventory, in the period from January 1, 2018 to the disposition of the Company's VIBATIV business in late 2018, was not material for the year ended December 31, 2018.

As of December 31, 2020, the unrecognized share-based compensation cost, net of actual forfeitures, and the estimated weighted-average amortization period, using the straight-line attribution method, was as follows:

(In thousands, except amortization period)	Unrecognized Compensation Cost	Weighted-Average Amortization Period (Years)
Theravance Biopharma equity:		
Options	$ 11,513	2.62
RSUs	101,588	2.53
Performance RSAs and RSUs [1]	502	0.21
ESPP	1,122	0.62
Total	$ 114,725	

(1) Represents unrecognized share-based compensation cost associated with the Company's performance-contingent awards described above that are probable of vesting.

Compensation Awards

The following table summarizes option activity under the 2013 EIP and 2014 NEEIP for the year ended December 31, 2020:

	Number of Shares Subject to Outstanding Options	Weighted-Average Exercise Price of Outstanding Options
Outstanding at December 31, 2019	2,950,472	$ 24.75
Granted	600,300	22.58
Exercised	(68,171)	19.96
Forfeited	(183,422)	22.49
Outstanding at December 31, 2020	3,299,179	$ 24.58

As of December 31, 2020, the aggregate intrinsic value of the options outstanding was $1.2 million. As of December 31, 2020, the aggregate intrinsic value of the options exercisable was $0.8 million. The total estimated fair value of options vested (excluding vested options that have expired) was $6.4 million in 2020.

The following table summarizes total RSU and RSA activity (including performance RSUs and RSAs) for the year ended December 31, 2020:

	Number of Shares Subject to Outstanding RSUs	Number of Shares Outstanding Subject to Performance Conditions (RSAs)
Outstanding at December 31, 2019	4,939,774	776,250
Granted	2,576,326	—
Released	(1,907,307)	(362,250)
Forfeited	(614,875)	—
Outstanding at December 31, 2020	4,993,918	414,000

As of December 31, 2020, the aggregate intrinsic value of the RSUs and RSAs outstanding was $88.7 million and $7.4 million, respectively. The total estimated fair value of RSUs vested was $46.8 million and $32.4 million in 2020 and 2019, respectively.

Valuation Assumptions

The range of assumptions used to estimate the fair value of options granted and rights granted under the 2013 ESPP was as follows:

	Year Ended December 31,		
	2020	2019	2018
Options			
Risk-free interest rate	0.3% - 1.7%	1.6% - 2.5%	2.3% - 3.0%
Expected term (in years)	5.2 - 6.1	6.0	6.0
Volatility	50% - 53%	51% - 53%	53% - 54%
Dividend yield	—	—	—
Weighted-average estimated fair value	$ 11.03	$ 10.20	$ 14.32
2013 ESPP			
Risk-free interest rate	0.1% - 0.2%	1.5% - 2.4%	2.1% - 2.8%
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Volatility	53% - 76%	40% - 48%	42% - 53%
Dividend yield	—	—	—
Weighted-average estimated fair value	$ 8.04	$ 6.17	$ 9.13

12. Income Taxes

Theravance Biopharma was incorporated in the Cayman Islands in July 2013 under the name Theravance Biopharma, Inc. as a wholly-owned subsidiary of Innoviva and began operations subsequent to the Spin-Off with wholly-owned subsidiaries in the Cayman Islands, US, United Kingdom, and Ireland. Effective July 1, 2015, Theravance Biopharma became an Irish tax resident, therefore, the loss before income taxes of Theravance Biopharma, the parent company, are included in Ireland in the tables below.

The components of the loss before income taxes were as follows:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Income (loss) before provision for income taxes:			
Cayman Islands	$ 37,567	$ 11,779	$ 14,838
United States	(46,500)	(99,225)	(69,695)
Ireland	(277,105)	(154,217)	(171,134)
United Kingdom	(499)	(14)	(94)
Total	$ (286,537)	$ (241,677)	$ (226,085)

The components of provision for income tax benefit (expense) were as follows:

	Year Ended December 31,		
(In thousands)	2020	2019	2018
Provision for income tax benefit (expense):			
Current:			
Cayman Islands	$ —	$ —	$ —
United States	8,545	5,210	10,563
Ireland	(13)	—	—
United Kingdom	(12)	12	(2)
Subtotal	8,520	5,222	10,561
Deferred	—	—	—
Total	$ 8,520	$ 5,222	$ 10,561
Effective tax rate	2.97 %	2.16 %	4.67 %

The provision for income tax benefit (expense) was $8.5 million, $5.2 million and $10.6 million for the year ended December 31, 2020, 2019 and 2018 respectively.

The 2020 net income tax benefit was primarily attributed to a reversal of previously accrued contingent tax liabilities for uncertain tax positions due to a lapse of the statute of limitations and their related interest accruals. The 2019 net income tax benefit was primarily due to the reversal of previously accrued contingent tax liabilities for uncertain tax positions due to a lapse of the statute of limitations and current year US research and development credits.

No provision for income taxes has been recognized on undistributed earnings of the Company’s foreign subsidiaries because it considers such earnings to be indefinitely reinvested. In the event of a distribution of these earnings in the form of dividends or otherwise, the Company may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits and foreign withholdings taxes payable to certain foreign tax authorities. As of December 31, 2020, there were no undistributed earnings.

As a result of the Company becoming an Irish tax resident effective July 1, 2015, the tax rates reflect the Irish statutory rate of 25%. The differences between the Irish statutory income tax rate and the Company's effective tax rates were as follows:

	Year Ended December 31,		
	2020	2019	2018
Provision at statutory income tax rate	25.00 %	25.00 %	25.00 %
Foreign rate differential	(11.49)	(6.96)	(7.51)
Share-based compensation	0.75	(1.17)	0.28
Non-deductible executive compensation	(0.63)	(0.51)	(0.72)
Uncertain tax positions	(1.26)	(0.63)	(4.00)
Research and development tax credit carryforwards	1.83	2.50	1.79
Foreign exchange loss	—	—	8.52
Intangible asset	10.01	—	—
Change in valuation allowance	(20.56)	(14.90)	(18.82)
Other	(0.68)	(1.17)	0.13
Effective tax rate	2.97 %	2.16 %	4.67 %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows:

	December 31,	
(In thousands)	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 82,821	$ 58,161
Capital loss carryforwards	19,409	19,409
Research and development tax credit carryforwards	24,075	15,723
Fixed assets and intangibles	310,187	285,341
Share-based compensation	15,087	15,480
Accruals	8,145	8,245
Operating lease liabilities	11,662	11,358
Other	346	7
Subtotal	471,732	413,724
Valuation allowance	(462,711)	(403,836)
Total deferred tax assets	9,021	9,888
Deferred tax liabilities:		
Operating lease assets	(8,680)	(9,429)
Prepaid assets	(341)	(459)
Total deferred tax liabilities	(9,021)	(9,888)
Net deferred tax assets (liabilities)	$ —	$ —

The Company follows 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 December 31, 2020, the Company's deferred tax assets were offset in full by a valuation allowance.

The valuation allowance as of December 31, 2020 increased from $403.8 million (the valuation allowance as of December 31, 2019) to $462.7 million, primarily as a result of additional tax loss generated in various jurisdictions during the current year and the intercompany transfer of intangible assets eligible for tax amortization. Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that the deferred tax assets are recoverable. As required, the Company prepares its assessment of the realizability of deferred tax assets on a jurisdiction-by-jurisdiction basis.

As of December 31, 2020, the Company had $209.8 million of US federal net operating loss carryforwards and $21.1 million of federal research and development tax credit carryforwards which expire beginning in 2035. After the enactment of the Tax Cut and Jobs Act (the "Tax Act") in December 2017, the operating losses generated had an indefinite carryforward life, but was limited to 80% of taxable income when utilized. As of December 31, 2020, this amount was $164.9 million. The Company had state net operating loss carryforwards of $70.9 million which generally begin to expire in 2034 and state research and development credit carryforwards of $21.2 million to be carried forward indefinitely.

The Company also had Irish net operating loss carryforwards of $565.8 million with no expiration date and capital loss carryforwards of $58.8 million to be carried forward indefinitely.

Utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The amount of tax expense related to interest or penalties was immaterial for the year ended December 31, 2020 and 2019.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the total amounts of unrecognized tax benefits were as follows:

(In thousands)	
Unrecognized tax benefits as of December 31, 2018	$ 52,404
Gross decrease in tax positions for prior years	(2,010)
Gross increase in tax positions for current year	8,369
Unrecognized tax benefits as of December 31, 2019	58,763
Gross decrease in tax positions for prior years	(8,059)
Gross increase in tax positions for current year	12,743
Unrecognized tax benefits as of December 31, 2020	$ 63,447

The Company records 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. The Company includes any applicable interest and penalties within the provision for income taxes in the consolidated statements of operations.

The total unrecognized tax benefits of $63.4 million and $58.8 million, as of December 31, 2020 and December 31, 2019, respectively, may reduce the effective tax rate in the period of recognition. However, carryforward tax attributes that were generated in years beginning on or before January 1, 2018 may still be adjusted upon examination by tax authorities since the attributes are not yet utilized. The Company does not expect to record any other material reductions in the measurement of its unrecognized tax benefits within the next twelve months. The Company currently has a full valuation allowance against its deferred tax assets, which would impact the timing of the effective tax rate benefit should any of these uncertain positions be favorably settled in the future.

The Company is subject to taxation in Ireland, the US, and various other jurisdictions. The tax years 2017 and forward remain open to examination in Ireland, tax years 2018 and forward remain open to examination in the US, and the tax years 2015 and forward remain open to examination in other jurisdictions.

The Company is currently under Internal Revenue Service ("IRS") examination for the tax year ended December 31, 2018. The Company believes that an adequate provision has been made for any material adjustments that may result from the tax examination. The Company concluded its IRS examination for the tax year ended December 31, 2017 in December 2020 with no adjustments required.

On March 27, 2020, the *Coronavirus Aid, Relief, and Economic Security Act* (the "CARES Act"), that features significant tax provision and other measures to assist individuals and businesses impacted by the economic effects of the COVID-19 pandemic, was signed into law. Tax relief measures for businesses include a five-year net operating loss carryback (including a related technical correction to the 2017 Tax Reform Act), a change in Section 163(j) interest deduction limitations, accelerated alternative minimum tax refunds, payroll tax relief, a temporary suspension of certain aviation excise taxes, a tax credit for employers who retain employees, and a 'qualified improvement property' technical correction to the 2017 Tax Reform Act. The Company has considered the corporate income tax provisions of the CARES Act and related initial guidance as part of its income tax expense and concluded that these provisions did not have a material impact on the Company's 2020 income tax expense.

The Company's future income tax expense may be affected by such factors as changes in tax laws, its 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, its 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.

13. Commitments and Contingencies

Performance-Contingent Awards

In 2016, the Compensation Committee granted long-term retention RSAs and RSUs to members of senior management 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 it believes the goals, if achieved, should increase shareholder value. The awards have dual triggers of vesting based upon the achievement of these goals and continued employment.

Expense associated with these awards may be recognized during the years 2016 to 2020 depending on the probability of meeting certain 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. Previously recognized expense is reversed in the period in which it becomes probable that the requisite service period will not be rendered. The awards are broken into three separate tranches and comprised of a share-based award component and a cash bonus award component. See *"Note 11. Share-Based Compensation"* for information related to the share-based award component.

The performance conditions associated with the first tranche of the cash bonus awards were completed in the second quarter of 2018, and the Company recognized $3.5 million of cash bonus expense for the year ended December 31, 2018 associated with the first tranche of these awards.

The performance conditions associated with the second tranche of these awards were completed in the first quarter of 2019 and the expense associated with this second tranche was fully recognized in the first quarter of 2020. For year ended December 31, 2020, 2019 and 2018, the Company recognized $0.5 million, $2.4 million and $1.9 million, respectively, of cash bonus expense related to the second tranche of these awards.

In the fourth quarter of 2019, the Company determined that the remaining third tranche was probable of vesting, and in the first quarter of 2020, the performance conditions associated with the third tranche were completed. As a result, the Company recognized $2.8 million and $11.8 million in cash bonus expense related to these awards for the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the maximum remaining cash bonus expense

associated with the third tranche was $0.4 million (allocated as $0.3 million for research and development expense and $0.1 million for selling, general and administrative expense) and will be amortized through the first quarter of 2021.

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2020 and 2019.

14. Public Offering of Ordinary Shares

On February 14, 2020, the Company sold 5,500,000 ordinary shares at a price to the public of $27.00 per share (the “Shares”). The gross proceeds to the Company from the offering were $148.5 million, before deducting underwriting discounts and commissions and offering expenses. The Shares were issued pursuant to the Company’s currently effective shelf registration statement on Form S-3 and an accompanying prospectus (File No. 333-235339) filed with the SEC, which became effective automatically on December 3, 2019, and a prospectus supplement filed with the SEC in connection with the offering.

15. Reduction in Workforce

In January 2019, the Company announced a reduction in workforce to align with its focus on continued execution of key strategic programs and advancement of selected late-stage research programs toward clinical development. The Company reduced its overall headcount by 51 individuals, with the affected employees primarily focused on early research or the infrastructure in support of VIBATIV, which was sold by the Company to Cumberland in November 2018.

As a result of the reduction in workforce, the Company recognized and paid severance related charges totaling $3.5 million for the year ended December 31, 2019, including compensation expense made to affected employees through any minimum statutory notice periods. The severance related charges are presented on the consolidated statements of operations within research and development expenses and selling, general and administrative expenses.

SUPPLEMENTARY FINANCIAL DATA
(UNAUDITED)
(In thousands, except per share data)

The following table presents certain unaudited consolidated quarterly financial information for the eight quarters in the periods ended December 31, 2020 and 2019. This information has been prepared on the same basis as the audited consolidated financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the unaudited quarterly results of operations set forth herein.

	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2020				
Total revenue	$ 19,862	$ 15,008	$ 18,257	$ 18,730
Costs and expenses	92,338	87,184	94,872	95,220
Loss from operations	(72,476)	(72,176)	(76,615)	(76,490)
Net loss	(83,053)	(62,887)	(73,643)	(58,434)
Basic and diluted net loss per share	$ (1.40)	$ (1.00)	$ (1.16)	$ (0.92)
2019				
Total revenue	$ 5,338	$ 26,150	$ 12,427	$ 29,499
Costs and expenses	79,004	68,626	77,628	100,071
Loss from operations	(73,666)	(42,476)	(65,201)	(70,572)
Net loss	(72,580)	(39,838)	(58,431)	(65,606)
Basic and diluted net loss per share	$ (1.32)	$ (0.72)	$ (1.05)	$ (1.17)

Share of Total YUPELRI Net Sales [(1)]

	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
2020	$ 12,880	$ 10,589	$ 12,960	$ 13,550
2019	$ 1	$ 3,184	$ 5,763	$ 10,352

(1) The Company co-promotes YUPELRI in the US under a profit and loss sharing arrangement with Viatris (65% to Viatris; 35% to Theravance Biopharma). The amounts represent the Company's implied 35% share of the total net sales of YUPELRI that were recognized within Viatris' financial statements for the periods presented.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. 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 December 31, 2020, 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. In connection with the preparation of this Annual Report, our management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020 based on criteria established in *Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission* (2013 framework) (the "COSO criteria"). Based on its assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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 fourth quarter of the year ended December 31, 2020 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting despite the fact that many of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the potential impact of COVID-19 on our internal controls to minimize the impact on their design and operating effectiveness.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Theravance Biopharma, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Theravance Biopharma, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Theravance Biopharma, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2020 consolidated financial statements of the Company and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's 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 generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

/s/ Ernst & Young LLP

Redwood City, California
February 26, 2021

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

For the information required by this Item, see “Questions and Answers About Procedural Matters”, “Election of Directors”, “Nominees”, “Audit Committee”, “Meetings of the Board of Directors”, “Code of Conduct”, “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

For the information required by this Item, see “Director Compensation”, “Executive Compensation” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

For the information required by this Item, see “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

For the information required by this Item, see “Director Independence” and “Policies and Procedures for Related Party Transactions” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

For the information required by this Item, see “Ratification of the Appointment of Independent Registered Public Accounting Firm” and “Pre-Approval of Audit and Non-Audit Services” in the Proxy Statement to be filed with the SEC, which sections are incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements:

The following financial statements and schedules of the Registrant are contained in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K:

2. Financial Statement Schedules:

All schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements, financial notes or supplementary financial information.

(b) Exhibits required by Item 601 of Regulation S-K

The information required by this Item is set forth on the exhibit index that precedes the signature page of this report.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
2.1	Separation and Distribution Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014	8-K	June 3, 2014
2.2*	Asset Purchase Agreement, dated as of November 1, 2018, by and among Cumberland Pharmaceuticals Inc. on the one hand, and Theravance Biopharma Ireland Limited and Theravance Biopharma US, Inc. on the other hand.	8-K	November 16, 2018
3.1	Amended and Restated Memorandum and Articles of Association	10-12B	April 30, 2014
4.1	Specimen Share Certificate	10-12B	April 30, 2014
4.2	Registration Rights Agreement, dated March 3, 2014	10-12B	April 8, 2014
4.3	First Amendment of Registration Rights Agreement, dated February 10, 2020 by and between Theravance Biopharma, Inc. and Glaxo Group Limited	10-Q	March 31, 2020
4.4	Shelf Rights Plan Resolution	DEF 14A	March 21, 2018
4.5	Sales Agreement between Theravance Biopharma, Inc. and Cowen and Company, LLC dated December 3, 2019	S-3	December 3, 2019
4.6	Indenture, dated as of November 2, 2016, between Theravance Biopharma, Inc. and Wells Fargo Bank, National Association, as trustee	8-K	November 2, 2016
4.7	First Supplemental Indenture, dated as of November 2, 2016, between Theravance Biopharma, Inc. and Wells Fargo Bank, National Association, as trustee	8-K	November 2, 2016
4.8	Form of 3.25% Convertible Senior Note due 2023 (included in Exhibit 4.6)	8-K	November 2, 2016
4.9	Indenture, dated as of February 28, 2020, by and among Triple Royalty Sub II LLC, as issuer, U.S. Bank National Association, as initial trustee, transfer agent, paying agent, registrar and calculation agent and, solely with respect to Section 2.11(o) and Section 2.11(p) Theravance Biopharma, Inc.	8-K	March 04, 2020
4.10	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	December 31, 2019
4.11	Registration Rights Agreement among Theravance Biopharma, Inc., GSK Finance (No.3) plc and GlaxoSmithKline plc dated June 22, 2020.	8-K	June 25, 2020
4.12	Waiver and Assignment of Registration Rights and Voting Agreement among GSK Finance (No.3) plc, Glaxo Group Limited and Theravance Biopharma, Inc. dated as of June 22, 2020.	8-K	June 25, 2020
10.1	Transition Services Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014	8-K	June 3, 2014
10.2	Tax Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 2, 2014	8-K	June 3, 2014
10.3	Employee Matters Agreement by and between Theravance Biopharma, Inc. and Innoviva, Inc., dated June 1, 2014	8-K	June 3, 2014
10.4+	2013 Equity Incentive Plan	S-8	August 18, 2014
10.5+	UK Addendum to the 2013 Equity Incentive Plan	10-Q	August 14, 2014
10.6+	2014 New Employee Equity Incentive Plan	S-8	November 14, 2014
10.7+	2013 Employee Share Purchase Plan, as amended	S-8	Aug. 18, 2014
10.8+	Forms of award agreements under the 2013 Equity Incentive Plan and 2014 New Employee Equity Incentive Plan	10-Q	May 10, 2016
10.9+	Forms of Equity Award Amendment	10-12B	May 7, 2014
10.10+	Form of TFIO Cash Award Amendment	10-12B	May 7, 2014
10.11+	Form of Acknowledgment for Irish Non-Employee Directors	10-K	March 11, 2016

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.12+	Irish Addendum to the 2013 Equity Incentive Plan	10-K	March 11, 2016
10.13+	Irish Addendum to the 2014 New Employee Equity Incentive Plan	10-K	March 11, 2016
10.14+	UK and Irish Addendums to the 2013 Employee Share Purchase Plan	10-K	March 11, 2016
10.15+	Theravance Biopharma, Inc. Performance Incentive Plan	8-K	May 6, 2016
10.16+	Form of Notice of Option Grant and Option Agreement under the Company's Performance Incentive Plan	10-Q	November 8, 2017
10.17+	Form of Notice of Performance Restricted Share Unit Award and Restricted Share Unit Agreement under the Company's Performance Incentive Plan	10-Q	November 8, 2017
10.18+	Change in Control Severance Plan	10-12B	April 8, 2014
10.19+	Cash Bonus Program	10-12B	November 22, 2013
10.20+	Form of Indemnity Agreement	10-12B	April 30, 2014
10.21	Amended and Restated Lease Agreement, 951 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	August 1, 2013
10.22	First Amendment to Lease for 951 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-12B	August 1, 2013
10.23	Lease Agreement, 901 Gateway Boulevard, between Innoviva, Inc. and HMS Gateway Office L.P., dated January 1, 2001	10-12B	August 1, 2013
10.24	First Amendment to Lease for 901 Gateway Boulevard effective as of June 1, 2010 between Innoviva, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-12B	August 1, 2013
10.25	Consent to Assignment by and among ARE-901/951 Gateway Boulevard, LLC, Innoviva, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 901 Gateway Blvd.	10-Q	August 14, 2014
10.26	Consent to Assignment by and among ARE-901/951 Gateway Boulevard, LLC, Innoviva, Inc. and Theravance Biopharma, Inc. and Assignment and Assumption of Lease for 951 Gateway Blvd.	10-Q	August 14, 2014
10.27	Theravance Respiratory Company, LLC Limited Liability Company Agreement, dated May 31, 2014	8-K	June 3, 2014
10.28*	Technology Transfer and Supply Agreement, dated as of May 22, 2012 between Innoviva, Inc. and Hospira Worldwide, Inc.	10-12B	May 7, 2014
10.29*	First Amendment to the Technology Transfer and Supply Agreement by and between Innoviva, Inc. and Hospira Worldwide, Inc., dated May 16, 2013	10-Q	November 9, 2016
10.30*	Second Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Antibiotics, Inc. and Hospira Worldwide, Inc., dated October 17, 2014	10-Q	November 9, 2016
10.31*	Third Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Ireland Limited and Hospira Worldwide, Inc., dated April 14, 2016	10-Q	November 9, 2016
10.32*	Fourth Amendment to the Technology Transfer and Supply Agreement by and between Theravance Biopharma Ireland Limited and Pfizer CentreOne group of Pfizer, Inc., dated September 29, 2016	10-Q	November 9, 2016
10.33	Amendment No. 1 to the License, Development, and Commercialization Agreement by and between Theravance Biopharma Ireland Limited and Clinigen Group PLC dated August 4, 2016	10-Q	August 9, 2016
10.34	License Agreement with Janssen Pharmaceutica, dated as of May 14, 2002	10-Q	August 14, 2014
10.35	Collaboration Agreement between Innoviva, Inc. and Glaxo Group Limited, dated November 14, 2002 (1)		
10.36	Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated March 30, 2004 (2)		
10.37	Amendment to Strategic Alliance Agreement by and between Innoviva, Inc. and Glaxo Group Limited, dated October 3, 2011 (3)		

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.38	Collaboration Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014 (4)		
10.39	Strategic Alliance Agreement Amendment by and between Innoviva, Inc. and Glaxo Group Limited dated, March 3, 2014 (4)		
10.40	Master Agreement by and between Innoviva, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (4)		
10.41	Extension Agreement by and between the Company and Glaxo Group Limited, dated March 3, 2014	10-12B	April 8, 2014
10.42+	Amended Offer Letter with Rick E Winningham dated August 5, 2014	10-Q	November 12, 2014
10.43+	Offer Letter with Frank Pasqualone May 12, 2014	10-Q	August 14, 2014
10.44+	Offer Letter with Brett K. Haumann dated May 12, 2014	10-Q	August 14, 2014
10.46+	Offer Letter with Brad Shafer dated August 20, 2014	10-Q	November 12, 2014
10.48+	Offer Letter with Ken Pitzer September 15, 2014	10-Q	May 10, 2016
10.49+	Offer Letter with Phil Worboys September 9, 2014	10-Q	May 10, 2016
10.50+	Offer Letter with Richard Graham, Ph.D. dated August 12, 2015	10-Q	September 30, 2020
10.51**	Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015		
10.52*	License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Millennium Pharmaceuticals, Inc. dated June 8, 2016	10-Q	August 9, 2016
10.53	Form of Note Purchase Agreement, dated February 21, 2020 by and among Theravance Biopharma R&D, Inc., Triple Royalty Sub II LLC, and the Purchasers	10-K	December 31, 2019
10.54	Sale and Contribution Agreement, dated as of February 28, 2020, among Theravance Biopharma R&D, Inc., as the transferor, Triple Royalty Sub II LLC, as the transferee, and Theravance Biopharma, Inc.	8-K	March 04, 2020
10.55	Pledge and Security Agreement, dated as of February 28, 2020, between Theravance Biopharma R&D, Inc., as the equity holder, and U.S. Bank National Association, as the trustee	8-K	March 04, 2020
10.56	Servicing Agreement, dated as of February 28, 2020, between Triple Royalty Sub II LLC and Theravance Biopharma US, Inc.	8-K	March 04, 2020
10.57	Account Control Agreement, dated as of February 28, 2020, among Triple Royalty Sub II LLC, as the grantor, Theravance Biopharma US, Inc., as the servicer, U.S. Bank National Association, as the secured party, and U.S. Bank National Association, as the financial institution	8-K	March 04, 2020
10.58	Amended and Restated Limited Liability Company Agreement of Triple Royalty Sub II LLC, dated February 28, 2020, by Theravance Biopharma R&D, Inc., as the initial sole equity member	8-K	March 04, 2020
10.59	Annex A - Rules of Construction and Defined Terms of the Amended and Restated Limited Liability Company Agreement of Triple Royalty Sub II LLC, dated February 28, 2020	8-K	March 04, 2020
10.60**	License and Collaboration Agreement by and between Theravance Biopharma Ireland Limited and Janssen Biotech, Inc. dated as of February 5, 2018		
10.61+	Memorandum to Brett K. Haumann regarding Transfer to Transfer to Theravance Biopharma UK Limited, executed April 1, 2020	10-Q	March 31, 2020
10.62	Amendments to Lease for 901 Gateway Boulevard between Theravance Biopharma US, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-Q	August 2, 2018
10.63	Amendments to Lease for 951 Gateway Boulevard between Theravance Biopharma US, Inc. and ARE-901/951 Gateway Boulevard, LLC	10-Q	August 2, 2018
10.64	Agreement and General Release between Theravance Biopharma US, Inc. and Shehnaaz Suliman, dated March 1, 2019	10-Q	May 10, 2019
10.65	Offer Letter with Andrew Hindman dated May 30, 2019	10-Q	August 5, 2019

Exhibit Number	Description	Incorporated by Reference	
		Form	Filing Date/Period End Date
10.66*	Amendment No. 1 to the Development and Commercialization Agreement by and between Theravance Biopharma Ireland Limited and Mylan Ireland Limited, dated June 12, 2019	10-Q	August 5, 2019
10.67**	License Agreement by and between Theravance Biopharma Ireland Limited and Pfizer Inc. dated December 21, 2019	10-K	December 31, 2019
10.68+	Service Agreement by and between Brett K. Haumann and Theravance Biopharma UK Limited, dated April 1, 2020	10-Q	March 31, 2020
10.69	Cooperation Agreement among Theravance Biopharma, Inc., GSK Finance (No.3) plc and GlaxoSmithKline plc dated June 22, 2020	8-K	June 25, 2020
21.1	Subsidiaries of Theravance Biopharma, Inc.		
23.1	Consent of Independent Registered Public Accounting Firm		
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K)		
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934		
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934		
32	Certifications Pursuant to 18 U.S.C. Section 1350		
101	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline Extensible Business Reporting Language (iXBRL) includes: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Shareholders' Deficit, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements.		
104	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101).		

\+ Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.

* Portions of this exhibit have been omitted and the omitted information has been filed separately with the Securities and Exchange Commission pursuant to an order granting confidential treatment.

** Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

(1) Incorporated by reference to an exhibit filed with the quarterly report on Form 10-Q of Innoviva, Inc., filed with the Securities and Exchange Commission on August 7, 2014.

(2) Incorporated by reference to an exhibit filed with the annual report on Form 10-K of Innoviva, Inc., filed with the Commission on March 3, 2014.

(3) Incorporated by reference to an exhibit filed with the annual report on Form 10-K of Innoviva, Inc., filed with the Commission on February 27, 2012.

(4) Incorporated by reference to an exhibit filed with the current report on Form 8-K/A of Innoviva, Inc., filed with the Commission on March 6, 2014.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THERAVANCE BIOPHARMA, INC.

Date: February 26, 2021

By: /s/ Rick E Winningham
Rick E Winningham
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Rick E Winningham as their true and lawful attorney-in-fact and agent, each with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to the annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Rick E Winningham Rick E Winningham	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 26, 2021
/s/ Andrew Hindman Andrew Hindman	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 26, 2021
/s/ Laurie Smaldone Alsup, M.D. Laurie Smaldone Alsup, M.D.	Director	February 26, 2021
/s/ Eran Broshy Eran Broshy	Director	February 26, 2021
/s/ Robert V. Gunderson, Jr. Robert V. Gunderson, Jr.	Director	February 26, 2021
/s/ Donal O'Connor Donal O'Connor	Director	February 26, 2021
/s/ Burton G. Malkiel, Ph.D. Burton G. Malkiel, Ph.D.	Director	February 26, 2021

Signature	Title	Date
/s/ Dean J. Mitchell Dean J. Mitchell	Director	February 26, 2021
/s/ Susan M. Molineaux, Ph.D. Susan M. Molineaux, Ph.D.	Director	February 26, 2021
/s/ Deepika R. Pakianathan, Ph.D. Deepika R. Pakianathan, Ph.D.	Director	February 26, 2021
/s/ George M. Whitesides, Ph.D. George M. Whitesides, Ph.D.	Director	February 26, 2021
/s/ William D. Young William D. Young	Director	February 26, 2021

DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Development and Commercialization Agreement ("Agreement") dated January 30, 2015 (the "Effective Date") is made by and between THERAVANCE BIOPHARMA R&D, INC., a Cayman Islands exempted company having its principal office at Ugland House, South Church Street, George Town, Grand Cayman, Cayman Islands E9 KY1-1104 ("THERAVANCE"), and MYLAN IRELAND LIMITED, a limited company organized and existing under the laws of Ireland with its offices at South Bank House, Barrow Street, 6th Floor, Dublin 4, Ireland ("MYLAN"). THERAVANCE and MYLAN may be referred to, individually, as a "Party" or, together, as the "Parties."

RECITALS

WHEREAS, THERAVANCE has discovered and is currently developing the proprietary long-acting muscarinic compound identified as TD-4208 for the treatment of respiratory disorders; and

WHEREAS, MYLAN and THERAVANCE desire to establish a broad collaboration for the development and commercialization of TD-4208 in a nebulized form, both as a standalone monotherapy and in combination or co-formulation with other chemically distinct and therapeutically active compounds.

NOW, THEREFORE THERAVANCE and MYLAN, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

Section 1.01 "Adverse Drug Experience" means any of: an "adverse drug experience/reaction," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience," in each case as defined in the Federal Food Drug and Cosmetic Act, or any comparable experience, response or reaction associated with a pharmaceutical product that is reportable to Governmental Authorities in jurisdictions outside of the United States pursuant to applicable Laws.

Section 1.02 "Affiliate" of a Person means any other Person, whether de jure or de facto, that directly or indirectly controls, is controlled by, or is under common control with such Person for so long as such control exists, where "control" means the decision-making authority to control the management of such other Person whether by ownership,

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

contract or otherwise; and, further, where such control shall be presumed to exist where a Person owns more than fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of any Person.

Section 1.03 "API Compound" means the active pharmaceutical ingredient compound of TD-4208, prior to the commencement of secondary manufacturing.

Section 1.04 "Approval Batch" means any validation, confirmation or scale-up batch of Licensed Product in the Field manufactured in support of Marketing Authorization.

Section 1.05 "Breaching Party" shall have the meaning set forth in Section 13.02.

Section 1.06 "Business Day" means any day on which banking institutions in New York, New York are open for the conduct of normal banking business.

Section 1.07 "Calendar Quarter" means for each Calendar Year, each of the three-month periods ending on March 31, June 30, September 30 and December 31.

Section 1.08 "Calendar Year" means, for the first calendar year, the period commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and, thereafter during the Term, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.

Section 1.09 "cGMP" shall mean the Laws that apply to the manufacture of pharmaceuticals for administration to humans in the Territory or any country or jurisdiction therein, including: (a) the principles detailed in the U.S. Current Good Manufacturing Practices, including 21 C.F.R. Parts 210 and 211, (b) the current principles and guidelines of good manufacturing practices for medicinal products as set out in EU Directive 2003/94/EC, and (c) the principles detailed in the ICH Q7A guidelines.

Section 1.10 "Change of Control Conflict Company" means any Person listed on Exhibit H or an Affiliate of such Person.

Section 1.11 "China" means the People's Republic of China, including the Hong Kong Special Administrative Region, the Macao Special Administrative Region and Taiwan.

Section 1.12 "China Notice" shall have the meaning set forth in Section 2.07.

Section 1.13 "China Notice Date" shall have the meaning set forth in Section 2.07(a).

Section 1.14 "China RFN" shall have the meaning set forth in Section 2.07.

Section 1.15 "Claim" means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

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Section 1.16 "CMC" shall have the meaning set forth in Section 4.01.

Section 1.17 "Combination Licensed Product" means any pharmaceutical composition or product that contains TD-4208 as an active ingredient that is packaged or formulated in combination with one or more other therapeutically active agents.

Section 1.18 "Commercialization" means any and all activities directed to marketing, advertising, promoting, distributing (including storing, transporting), detailing and otherwise offering for sale and selling Licensed Product, regardless of whether such activities occur prior to or after receipt of Marketing Authorization (including medical support planning) of such Licensed Product, including exporting or importing Licensed Product (to the extent applicable) for such purposes, conducting health economic studies and Phase 4 Studies, market research, and regulatory affairs and interactions with Governmental Authorities in support of the foregoing. For clarity, Commercialization includes any and all (a) Co-Promotion activities and (b) activities with respect to pricing, discounting, reimbursement and patient access for Licensed Product through all private and public channels. When used as a verb, "Commercialize" means to engage in Commercialization.

Section 1.19 "Commercial Budget" means the budget included as part of each Commercialization Plan, as updated annually for each Calendar Year or otherwise by the Parties in accordance with this Agreement, setting forth the anticipated spending required for executing the Commercialization Plan.

Section 1.20 "Commercialization Plan" means the comprehensive sales and marketing plan for a Licensed Product in the Field in the Territory described in Section 5.01.

Section 1.21 "Commercialization Plan Outline" means that outline attached hereto as Exhibit E that sets forth the elements to be included in each Commercialization Plan.

Section 1.22 "Competitive Product" shall have the meaning set forth in Section 5.06(a).

Section 1.23 "Confidential Information" means all secret, confidential or proprietary information, data or know-how (including MYLAN Know-How and THERAVANCE Know-How), whether provided in written, oral, graphic, video, computer or other form, provided by one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") pursuant to this Agreement or generated pursuant to this Agreement, including information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products, the terms of this Agreement and any other materials that have not been made available by the Disclosing Party to the general public. Confidential Information shall not include any information or materials that the Receiving Party can document with competent written proof:

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

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

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

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

(e) were independently discovered or developed by or on behalf of the Receiving Party without the use of, or reference to, the Confidential Information belonging to the other Party.

Notwithstanding the foregoing exceptions (a)-(e), inclusive, specific aspects of Confidential Information shall not be deemed to be within the foregoing exceptions when such exceptions apply only to more general information or when the relevant specific aspects are identified using Confidential Information.

Section 1.24 "Consensus" means, in the framework of the governance provisions set forth in Article 3 herein, agreement between the relevant representatives from each Party, with each Party's representatives on the applicable committee having, collectively, one vote, in each case as reflected in final written minutes of the applicable committee or other writing executed or acknowledged by an appropriate representative from each Party.

Section 1.25 "COPD" shall have the meaning set forth in Section 1.45.

Section 1.26 "Co-Promotion Agreement" shall have the meaning set forth in Section 5.03(c).

Section 1.27 "Cost of Goods Sold" or "COGS" means (a) with respect to Licensed Product manufactured by MYLAN or its Affiliates, the [***] and (b) with respect to Licensed Product purchased by MYLAN or its Affiliates from a Third Party, MYLAN or its Affiliate's [***], together in the case of (a) and (b) with [***], and together in the case of (b) with other costs [***] and allocable to such [***] in accordance with GAAP, including costs of [***]. For clarity, COGS shall include such costs with respect to [***]. In the event that any Licensed Product in the Field comprising Approval Batches are not sold commercially, the Parties will share the costs of such Approval Batches as follows: [***] by MYLAN and [***] by THERAVANCE.

Section 1.28 "Cost Overrun" shall have the meaning set forth in Section 4.02(d).

Section 1.29 "Country" means any sovereign entity generally recognized internationally as a nation (including all territories, protectorates and possessions thereof). For purposes of Patent-related activities under Article 12, Country shall also

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include member states, regions or territories that would be covered by a single patent application or patent pursuant to patent treaties, regional patent offices or patent organizations, including the Patent Cooperation Treaty (PCT), the European Patent Organization (EPO) and the Eurasian Patent Organization.

Section 1.30 "Creditable Taxes" shall have the meaning set forth in Section 6.06(c).

Section 1.31 "Date of Termination" shall have the meaning set forth in Section 14.02.

Section 1.32 "Development" or "Develop" means any and all preclinical and clinical drug development activities (other than Phase 4 Studies), including: test method development and stability testing, toxicology, formulation, process development, conducting clinical trials, development-stage manufacturing and clinical supply, scale up of the proposed commercial manufacturing process, current Good Manufacturing Practices audits conducted with respect to product intended for use in clinical studies, current Good Clinical Practices audits, current Good Laboratory Practices audits, analytical method transfer and validation, manufacturing process validation, cleaning validation, quality assurance/quality control development, statistical analysis and report writing, preclinical and clinical studies, regulatory filing preparation, submission, prosecution and approval, and regulatory affairs related to the foregoing and all other activities necessary or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining Marketing Authorization, in each case other than Phase 4 Studies and any of the foregoing activities to the extent associated with Phase 4 Studies. When used as a verb, "Develop" means to engage in Development. For clarity, Development excludes all activities comprising Commercialization.

Section 1.33 "Development Annual Fully Burdened FTE Rate" means the amount THERAVANCE attributes during the Term to support one Full Time Equivalent performing work under the Development Plan, which on the Effective Date is [***]. Such amount may be increased by the average of the percentage increase, if any, in each of (i) salaries reported for the current fiscal year by Radford Surveys™ Quarterly Salary Increase Trend Survey (QSIT)-Biotechnology Edition Base Salary Increase Analysis for Exempt Employees (Current Fiscal Year Actual (Undiluted) Overall Increases Combined) and (ii) Consumer Price Index, for All Urban Consumers for the San Francisco Bay Area, as published by the U.S. Department of Labor, Bureau of Labor Statistics, in the then current reported year over the immediately preceding reported year (or in the case of the first such increase, the Effective Date), on January 1, 2016 and annually thereafter during the Term. Otherwise the Development Annual Fully Burdened FTE Rate shall not be increased without the prior written consent of MYLAN.

Section 1.34 "Development Budget" means a part of the Development Plan for the entire Development project for the Licensed Product in the Field in the Territory and for each Calendar Year, capturing the anticipated spending required for executing the Development Plan.

Section 1.35 "Development Expenses" means the costs incurred by THERAVANCE in connection with the Development of the Licensed Product in the Field. These expenses

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will be comprised only of (a) THERAVANCE's actual external costs for the performance of the Development activities set forth in the Development Plan and (b) THERAVANCE's Development Annual Fully Burdened FTE Rate attributable to the time THERVANCE FTEs devoted to the performance of the Development activities set forth in the Development Plan. For clarity, (i) filing fees (including PDUFA fees) associated with any NDA or MAA ("Filing Fees") shall be Development Expenses, (ii) the costs of Approval Batches for the U.S. shall be COGS (and not Development Expenses), and (iii) [***] of the costs of Licensed Product comprising Approval Batches for the ROW Countries that is not actually sold shall be borne by THERAVANCE.

Section 1.36 "Development Plan" shall have the meaning set forth in Section 4.01.

Section 1.37 "Diligent Efforts" means the carrying out of obligations with respect to the Development, manufacture and Commercialization of Licensed Products in the Field in a sustained commercially reasonable manner consistent with the efforts a Party devotes (or would devote) to a product of similar market potential, profit potential and strategic value resulting from its own research efforts, based on conditions then prevailing; provided that, at a minimum, Diligent Efforts requires that: (i) each Party assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (ii) each Party set, monitor and seek to achieve such obligations; and (iii) each Party make and implement decisions and allocate resources designed to advance progress with respect to such objectives. For clarity, (a) Diligent Efforts shall be evaluated on a country-by-country basis based on all factors relevant to such country (including size of market, availability of alternative treatments, pricing strategies, likelihood of gray-market goods, applicable Law and the likelihood of obtaining a Marketing Authorization and (b) it is acknowledged that efforts would be reduced with respect to a product from and after the launch of a generic equivalent thereof.

Section 1.38 "Disclosing Party" shall have the meaning set forth in Section 1.23.

Section 1.39 "Divest" and "Divestiture" shall have the meaning set forth in Section 5.06(b).

Section 1.40 "DMF" means a drug master file submitted to the FDA, (or comparable document set submitted to any regulatory authority in the Territory, including the EMA).

Section 1.41 "Effective Date" shall have the meaning set forth in the preamble to this Agreement.

Section 1.42 "EMA" means the European Medicines Authority.

Section 1.43 "EU" means, collectively, the Countries of the European Union.

Section 1.44 "FDA" means the United States Food and Drug Administration and any successor agency thereto.

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Section 1.45 "Field" means the treatment of chronic obstructive pulmonary disease ("COPD"), asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any and all nebulized inhalation product presentations. For the avoidance of doubt, the term "Field" excludes the treatment of chronic obstructive pulmonary disease, asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any delivery mechanism other than a nebulized inhalation product presentation (such as in a metered dose inhaler or dry powder inhaler). For purposes of this definition, "treatment" means, with respect to a particular indication, the cure, reduction, mitigation, prevention, slowing or halting the progress of, or other management of such indication or its symptoms.

Section 1.46 "First Commercial Sale" means with respect to a particular Licensed Product in the Field, the first shipment of commercial quantities of such Licensed Product sold to a Third Party by a Party, its Affiliates and/or their sublicensees and/or distributors after receipt of Marketing Authorization for such Licensed Product in the Field. Sales for test marketing, sampling and promotional uses, named patient programs, clinical trial purposes or emergency or similar uses shall not be considered to constitute a First Commercial Sale.

Section 1.47 "Force Majeure Event" shall have the meaning set forth in Section 15.03.

Section 1.48 "FTE" or "Full-Time Equivalent" means the contribution of time equivalent to one (1) year of a full-time employee proficient in the performance of duties assigned to such employee under the Development Plan. One Full-Time Equivalent may be comprised of a single employee's time, or percentages of multiple employees' time which, together, equal 100%. The portion of an FTE year devoted by an employee to duties under the Development Plan shall be determined by dividing the number of full days during any twelve-month period devoted by such employee to such duties by the total number of working days during such twelve-month period.

Section 1.49 "GAAP" shall have the meaning set forth in Section 6.03.

Section 1.50 "Governmental Authority" means any court, tribunal, arbitrator, agency, department, legislative body, commission, official or other instrumentality of (i) any government of any Country or supra-national body or (ii) a federal, state, province, county, city or other political subdivision thereof, in each case having authority over the activities hereunder.

Section 1.51 "Hatch-Waxman Certification" shall have the meaning set forth in Section 12.04.

Section 1.52 "Hold Separate Transaction" shall have the meaning set forth in Section 5.06(b).

Section 1.53 "Housemark" means the corporate name and logo of MYLAN 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 Licensed Products in the Field.

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Section 1.54 "IND" means an investigational new drug application as defined under the Federal Food, Drug and Cosmetic Act.

Section 1.55 "Indemnified Party" shall have the meaning set forth in Section 11.03(a).

Section 1.56 "Indemnifying Party" shall have the meaning set forth in Section 11.03(a).

Section 1.57 "Invention" means any discovery or new technical idea (whether patentable or not) made (i.e., invented, created or otherwise developed) during the Term that is related to TD-4208 or a Licensed Product as a result of research, manufacturing, Development or Commercialization of the Licensed Products pursuant to this Agreement.

Section 1.58 "Joint Invention" means an Invention made jointly by an employee or agent of THERAVANCE or its Affiliates and an employee or agent of MYLAN or its Affiliates.

Section 1.59 "Joint Invention Patents" means all Patents claiming Joint Inventions. Joint Invention Patents include those Patents that may be set forth under "Joint Invention Patents" in Exhibit B after the Effective Date through an update to Exhibit B under Section 2.06.

Section 1.60 "Joint Product Committee" or "JPC" shall have the meaning set forth in Section 3.02(b).

Section 1.61 "Joint Steering Committee" or "JSC" shall have the meaning set forth in Section 3.01(a).

Section 1.62 "Labeling" means any and all labels, labeling, packaging package inserts and outserts, labels for Samples, and Promotional Materials for the Licensed Product in the Field in the Territory.

Section 1.63 "Laws" means all federal, state, local, and international equivalent laws, statutes, rules, regulations and guidances of Governmental Authorities, including, as applicable: (i) the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated pursuant thereto; (ii) standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, including but not limited to standards and guidances promulgated by the International Conference on Harmonization and the Declaration of Helsinki; (iii) the Clinical Laboratory Improvement Amendments of 1988; (iv) applicable privacy laws, including the Health Insurance Portability and Accountability Act of 1996; and (v) ordinances and other pronouncements of any Governmental Authority having the binding effect of law.

Section 1.64 "Licensed Product(s)" means any pharmaceutical composition or product that contains TD-4208 as an active ingredient, alone or in combination or co-formulation with other chemically distinct and therapeutically active compounds. For clarity, Licensed Products include Stand Alone Licensed Products and Combination Licensed Products.

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Section 1.65 "Litigation Condition" shall have the meaning set forth in Section 11.03(b).

Section 1.66 "Long Acting Muscarinic Antagonist" or "LAMA" means an inhaled agent that selectively binds muscarinic acetylcholine receptors, blocking or inhibiting M3 muscarinic acetylcholine receptor activity, and has a duration of action sufficient to require dosing no more than twice per day for the treatment of respiratory disorders in humans. LAMAs include tiotropium, glycopyrrolate/glycopyrronium, umeclidinium, aclidinium, oxitropium and dexpyrronium.

Section 1.67 "Losses" means any and all damages (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including court costs, interest and reasonable fees of attorneys, accountants and other experts), in each case awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented out-of-pocket costs and expenses incurred by the Indemnified Party in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

Section 1.68 "MAA" means a marketing authorization application or any amendments or supplements thereto submitted to the EMA in the EU. For purposes of this Agreement, the term "MAA" shall also mean any comparable marketing authorization or approval filings in the other ROW Countries in the Territory.

Section 1.69 "Manufacturing Cost" means, with respect to Licensed Product, the fully allocated direct and indirect costs incurred by MYLAN or its Affiliates determined in accordance with GAAP and consistent with MYLAN's internal accounting practices, consistently applied, for the manufacture of Licensed Product (provided that any such indirect costs are reasonably allocable to such Licensed Product), which costs may include:

(a) the cost of materials (including API Compound), components, supplies and other resources directly or indirectly consumed, in each case including freight, insurance, shipping, packaging and other similar costs associated with acquiring such items;

(b) labor (including salaries, wages and current period employee benefits), including management salary and benefits allocable to the manufacture of Licensed Product;

(c) the net cost or credit of any value-added taxes or duties actually paid or utilized (and not reimbursed or reimbursable) on account of such Licensed Product;

(d) Third Party costs for the manufacture of Licensed Product, including facilities fees, transportation costs, customs, duty and transit insurance costs;

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(e) manufacturing variances (including expired raw materials and finished goods, scrap, maintenance costs and batches that do not conform to the applicable specifications) incurred in the manufacture of Licensed Product;

(f) costs for quality control/assurance (including the costs of quantities destroyed in quality control testing) of such Licensed Product, including the costs of inspection, rejection and return of components, materials or services; and

(g) other costs reasonably allocable to the manufacture of Licensed Product, including allocable occupancy, idle capacity (based on planned capacity for the Licensed Product in the Field consistent with the Development Plan or Commercialization Plan), depreciation and amortization, allocable facilities costs, general and other overhead.

For clarity, Manufacturing Cost shall exclude corporate overhead and any other costs not allocable to the manufacture of the Licensed Products hereunder.

Section 1.70 "Marketing Authorization" means, with respect to a Country, the regulatory authorization required to market and sell Licensed Product in such Country as granted by the relevant Governmental Authority, including any such pricing, labeling or reimbursement approvals.

Section 1.71 "Milestone" shall have the meaning set forth in Section 1.02(a) of Exhibit F.

Section 1.72 "MYLAN Invention" means an Invention invented solely or jointly by an employee or agent of MYLAN or its Affiliates (excluding Joint Inventions).

Section 1.73 "MYLAN Know-How" means all information directly relating to TD-4208 or Licensed Products in the Field, including all data, records, and regulatory filings relating to TD-4208, API Compound or a Licensed Product in the Field, which is necessary or useful for THERAVANCE to perform its obligations or exercise its rights under this Agreement, and which, during the Term, is (a) produced by MYLAN or any of its Affiliates or comes into their possession and control pursuant to this Agreement, (b) disclosed by MYLAN to THERAVANCE hereunder, or (c) used by or on behalf of MYLAN in its manufacture of API Compound or Licensed Product in the Field and, in each case (a), (b) and (c), is owned by, or licensed to, MYLAN (with the right to sublicense in accordance with this Agreement). MYLAN Know-How does not include any MYLAN Patents (other than the information contained in unpublished Patents). MYLAN Know-How shall exclude any information licensed to MYLAN for which it (a) requires consent from any Third Party and such consent is not obtained after using Diligent Efforts to do so or (b) requires any payment to a Third Party as a result of the grant or exercise of any license by or under authority of THERAVANCE or its Affiliates, unless in the case of (b), THERAVANCE agrees in writing to reimburse (and actually reimburses) MYLAN in advance for all amounts payable to such Third Party as a result of such grant or exercise and timely provides any additional information required by MYLAN's agreement with such Third Party in connection therewith.

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Section 1.74 "MYLAN Patents" means all Patents (excluding Joint Invention Patents) filed and owned by or licensed (with the right to grant sublicenses in accordance with this Agreement) to MYLAN or its Affiliates that claim a MYLAN Invention or a method of manufacture used by or on behalf of MYLAN in its manufacture of API Compound or Licensed Product in the Field hereunder. MYLAN Patents include those Patents set forth under "MYLAN Patents" in Exhibit B after the Effective Date through an update to Exhibit B under Section 2.06. MYLAN Patents shall exclude any Patents licensed to MYLAN for which it (a) requires consent from any Third Party and such consent is not obtained after using Diligent Efforts to do so or (b) requires any payment to a Third Party as a result of the grant or exercise of any license by or under authority of THERAVANCE or its Affiliates, unless in the case of (b), THERAVANCE agrees in writing to reimburse (and actually reimburses) MYLAN in advance for all amounts payable to such Third Party as a result of such grant or exercise and timely provides any additional information required by MYLAN's agreement with such Third Party in connection therewith.

Section 1.75 "MYLAN Product Trademarks" means any and all Trademarks and trade dress that MYLAN (or its Affiliates) may use, file to register or otherwise select and control in accordance with the terms of this Agreement, in each case for use on the Licensed Product(s) in the Field in the Territory during the Term. For clarity, "MYLAN Product Trademark" excludes any MYLAN Housemark but includes any other MYLAN corporate branding scheme (e.g. font color, type and size and related graphics) used on the Licensed Product(s) in the Field in the Territory during the Term.

Section 1.76 "NDA" means a new drug application or supplemental new drug application or any amendments thereto submitted to the FDA under the Federal Food, Drug and Cosmetic Act.

Section 1.77 "Net Sales" means the gross amount invoiced for the sale of Licensed Product in the Field by a Party, its Affiliates and/or their sublicensees to a Third Party, less the following: (a) cash, trade, prompt payment, quantity and other discounts actually given; (b) refunds, rebates, chargebacks, retroactive price adjustments, sales deductions, shelf stock or floor stock adjustments, billing errors, rejected goods, expired product, product recalls, and any other allowances actually given which effectively reduce the gross selling price; (c) credits and allowances for damaged goods and product returns; and (d) credits, charge-backs, discounts, rebates, reimbursements, fees and other allowances provided to distributors, wholesalers, pharmacies, selling agents (excluding sales representatives of a Party or any of its Affiliates), group purchasing organizations, and managed care entities, buying groups, health insurance carriers/agencies, government institutions/agencies, health care organizations and other institutions or customers; (e) freight, insurance and handling costs (to the extent not paid by the Third Party customer); and (f) sales tax, VAT and other taxes, duties or government charges levied on or measured by the billing amount, as adjusted for rebates or refunds, that are borne by the selling Party and that are not refundable and to the extent non-creditable. Net Sales shall exclude Samples distributed in the usual course of business. No individual deduction may be taken more than once in calculating Net Sales.

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Section 1.78 "Non-Neb Field" means the treatment of chronic obstructive pulmonary disease, asthma, cystic fibrosis and other respiratory diseases and conditions in humans via any delivery mechanism other than a nebulized inhalation product presentation.

Section 1.79 "Non-Neb Notice" shall have the meaning set forth in Section 2.08.

Section 1.80 "Non-Neb Notice Date" shall have the meaning set forth in Section 2.08(a).

Section 1.81 "Officers" shall have the meaning set forth in Section 3.01(f).

Section 1.82 "Operating Expense" means the sum of all costs incurred by the Parties or their Affiliates in connection with the Commercialization of Licensed Products in the Field in the U.S. in accordance with the Commercial Budget in the Commercialization Plan, including the following costs (i) advertising and promotion costs (including sales force costs, detailing and e-tailing; costs of developing and producing Promotional Materials, and marketing vendor costs; and costs of communications to healthcare providers, pharmacists, pharmacy and prescription benefit managers and formularies), (ii) medical affairs costs (including post-approval commitments and Phase 4 Studies other than those requested or required by a Regulatory Authority as a condition or in support of obtaining Marketing Authorization to the extent they are conducted prior to obtaining approval of the first NDA for the first Licensed Product in the Field), healthcare and consumer educational program costs, (iii) market research costs, and (iv) general administrative costs attributable to the Licensed Products in the Field. For clarity, no individual costs will be counted more than once and all Operating Expenses will be approved as a part of the Commercial Budget; provided that Commercialization expenses for the Licensed Products in the U.S. that are otherwise agreed by the Parties in writing outside of the Commercial Budget shall nevertheless be Operating Expenses shared by the Parties in accordance with Section 5.03(b) and Exhibit F.

Section 1.83 "Operating Profit (Loss)" means Net Sales less the following: (i) COGS, (ii) Operating Expense and (iii) Shared Expenses.

Section 1.84 "Patents" means patents and patent applications, including (a) provisional applications, continuation applications, continuations-in-part, divisional applications, Patent Cooperation Treaty applications and all patents issuing from such applications, (b) utility patents, design patents, reexaminations, reissues, registrations, confirmations, revalidations, certificates of addition, utility models and petty patents, and (c) extensions or restorations of terms thereof, supplementary protection certificates or any other such right, anywhere in the world.

Section 1.85 "Patent Infringement Claim" shall have the meaning set forth in Section 12.03(a).

Section 1.86 "Patent Infringement Notice" shall have the meaning set forth in Section 12.03(b).

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Section 1.87 "Patent Resolution Issue" shall have the meaning set forth in Section 12.02(h).

Section 1.88 "Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, joint venture, sole proprietorship or other business organization or entity.

Section 1.89 "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.

Section 1.90 "Phase 3 Clinical Trial" means a 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.

Section 1.91 "Phase 3 Safety Study" means that certain Phase 3 Clinical Trial of the Licensed Product in the Field planned to be conducted by THERAVANCE as of the Effective Date pursuant to Protocol No. 0128, entitled "A 52-week parallel group safety study of TD-4208 in COPD."

Section 1.92 "Phase 4 Study" means any clinical trial of a Licensed Product conducted after receipt of Marketing Authorization in the approved indication, which is required to maintain such Marketing Authorization or otherwise useful for Commercializing such Licensed Product.

Section 1.93 "Post-Approval Development Expenses" shall have the meaning set forth in Section 4.02(c).

Section 1.94 "Preliminary Development Plan" shall have the meaning set forth in Section 4.01.

Section 1.95 "Promotional Materials" means the written, printed, audio, video, graphic, or electronic advertising, promotional, public relations, educational and communication materials for marketing, advertising and promotion of Licensed Products in the Field in the Territory. For clarity, the term "Promotional Materials" does not include the official product label for the Licensed Product in the Field in the Territory, which is approved by the relevant Government Authority in connection with its approval of an MAA for such Licensed Product.

Section 1.96 "Public Announcement Matters" shall have the meaning set forth in Section 9.04.

Section 1.97 "Publications Policy" shall have the meaning set forth in Section 9.03.

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Section 1.98 "Receiving Party" shall have the meaning set forth in Section 1.23.

Section 1.99 "Recording Party" shall have the meaning set forth in Section 6.08.

Section 1.100 "Regulatory Authority" means any Governmental Authority responsible for granting Marketing Authorizations for a pharmaceutical or healthcare product in the Territory.

Section 1.101 "Regulatory Filings" means any submission made to a Regulatory Authority with respect to the Licensed Product, including any IND, NDA, Marketing Authorization Application, any submission to a regulatory advisory board, and any supplement or amendment to any of the foregoing.

Section 1.102 "Reverted Country" shall have the meaning set forth in Section 4.03(d).

Section 1.103 "RFN" shall have the meaning set forth in Section 2.08.

Section 1.104 "ROW" or "Rest of World" means worldwide but excluding the U.S. and China.

Section 1.105 "ROW Recall Costs" shall have the meaning set forth in Section 7.02.

Section 1.106 "Samples" means Licensed Product packaged and distributed as a complimentary trial for use by patients in the Field in the Territory after having obtained Marketing Authorization.

Section 1.107 "Shared Expenses" means Post-Approval Development Expenses, U.S. Recall Costs, and Enforcement Damages.

Section 1.108 "SPCs" shall have the meaning set forth in Section 12.02(g).

Section 1.109 "Stand Alone Licensed Product" means any pharmaceutical composition or product Developed under this Agreement that contains TD-4208 as the sole active ingredient (i.e. no combination or co-formulation with any other chemically distinct and therapeutically active compound).

Section 1.110 "Step-In Rights" shall have the meaning set forth in Section 12.02(d).

Section 1.111 "Sublicensee Improvement" shall have the meaning set forth in Section 2.04.

Section 1.112 "Supplied Licensed Product" shall have the meaning set forth in Section 14.02(a)(vii).

Section 1.113 "Taxes" shall have the meaning set forth in Section 6.06(a).

Section 1.114 "TD-4208" means the chemical compound known as TD-4208, together with all analogs, salts, esters, complexes, chelates, polymorphs, hydrates, isomers, stereoisomers, crystalline and amorphous forms, prodrugs, solvates, metabolites and

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metabolic precursors (whether active or inactive), and other structural derivatives thereof. The structure of TD-4208 is shown in Exhibit A.

Section 1.115 "Technology Transfer Package" means all THERAVANCE Confidential Information and THERAVANCE Know-How relating to the Licensed Product, including all information regarding the API Compound and formulated Licensed Product in the Field and methods of manufacturing the same, analytical methods, specifications, batch records, batch testing and release results, results and reports of all pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, other quality management system documentation supporting manufacture and release, results and reports of all non-clinical, pre-clinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, and regulatory correspondence.

Section 1.116 "Term" means, on a Licensed Product-by-Licensed Product basis and on a Country-by-Country basis, the period from the Effective Date until the later of (a) the expiration or termination of the last Valid Claim of a THERAVANCE Patent covering any Licensed Product in the Field, or (b) thirteen (13) years from First Commercial Sale anywhere in the Territory, unless this Agreement is terminated earlier in accordance with ARTICLE 13.

Section 1.117 "Territory" means worldwide, excluding China; provided that upon reversion, a Reverted Country shall no longer be included within the Territory.

Section 1.118 "THERAVANCE Invention" means an Invention invented solely or jointly by an employee or agent of THERAVANCE or its Affiliates (excluding Joint Inventions).

Section 1.119 "THERAVANCE Know-How" means all present and future information relating to TD-4208, API Compound or a Licensed Product, including all data, records, and Regulatory Filings relating to TD-4208, API Compound or a Licensed Product or THERAVANCE Invention, which is necessary or useful for MYLAN to perform its obligations or exercise its rights under this Agreement, and which is in THERAVANCE's or any of its Affiliates' possession or control and is or becomes owned by, or is licensed (with the right to sublicense) to, THERAVANCE or its Affiliates. THERAVANCE Know-How does not include any THERAVANCE Patents (other than the information contained in unpublished Patents), nor any THERAVANCE drug discovery research plans, strategies, tools, methods or processes for products other than Licensed Products in the Field.

Section 1.120 "THERAVANCE Patents" means all present and future Patents (excluding Joint Invention Patents) owned by or licensed to THERAVANCE or its Affiliates that claim the compound, compositions, or any method of making or using, TD-4208 or a Licensed Product or the THERAVANCE Know-How, including Patents claiming THERAVANCE Inventions. THERAVANCE Patents include those Patents set forth under "THERAVANCE Patents" in Exhibit B as of the Effective Date (or added through an update to Exhibit B under Section 2.06), and any and all Patents issuing from

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applications claiming common priority thereto. For purposes of clarity, "THERAVANCE Patents" includes any and all patents issuing, either from continuation or divisional applications, that claim priority to the following provisional applications: [***].

Section 1.121 "Third Party" means a Person who is not a Party or an Affiliate of a Party.

Section 1.122 "Third Party Claim" shall have the meaning set forth in Section 11.03(a).

Section 1.123 "Trademarks" shall have the meaning set forth in Section 2.05(a).

Section 1.124 "Transfer Date" shall have the meaning set forth in Section 7.01(a).

Section 1.125 "U.S." means the United States and its territories and possessions.

Section 1.126 "Upfront Payment" shall have the meaning set forth on Exhibit F.

Section 1.127 "Valid Claim" means an issued patent claim that has not: (i) expired; (ii) been held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal; or (iii) been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer.

Section 1.128 "VAT" means Value Added Tax in Ireland or any similar tax which may be imposed in the Territory and "VATCA" means the Irish Value Added Tax Consolidation Act 2010.

Section 1.129 "Withholding Party" shall have the meaning set forth in Section 6.06(a).

Section 1.130 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (v) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, 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 number also include the plural or singular number, respectively; (viii) references to any specific law, or article, section or other division

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thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof.

ARTICLE 2 RIGHTS AND OBLIGATIONS

Section 2.01 License Grants from THERAVANCE to MYLAN. Subject to the terms of this Agreement, THERAVANCE hereby grants to MYLAN, and MYLAN accepts:

(a) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Product in the Field worldwide for Commercialization in the Territory;

(b) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Commercialize Licensed Products in the Field in the Territory;

(c) an exclusive license under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to make and have made (i) API Compound for incorporation into Licensed Products in the Field and (ii) Licensed Products in the Field, in each case worldwide for purposes of Developing such Licensed Products for, and Commercializing such Licensed Product in, the Field in the Territory;

(d) a non-exclusive license to use THERAVANCE's Housemarks to the extent included on the Labeling of the Licensed Products in the Field, solely for purposes of manufacturing Licensed Products in the Field and Commercializing the Licensed Products in the Field in the Territory; and

(e) an exclusive license to otherwise exploit the THERAVANCE Patents and THERAVANCE Know-How and any Joint Invention Patents in connection with and within the scope of the licenses set forth in Sections 2.01(a)-(c) above.

Notwithstanding the foregoing, THERAVANCE and its Affiliates retain their rights under the THERAVANCE PATENTS and THERAVANCE KNOW-HOW and Joint Invention Patents to (x) Develop the Licensed Products in the Field for the Territory in accordance with the Development Plan, (y) manufacture the Licensed Products in the Field for purposes of clinical trials of the Licensed Products in the Field to be conducted in accordance with the Development Plan, and (z) Commercialize the Licensed Products in the Field in the U.S. in accordance with the Commercialization Plan, in each case solely in accordance with and pursuant to this Agreement. For clarity, THERAVANCE and its Affiliates retain all rights under the THERAVANCE PATENTS and THERAVANCE KNOW-HOW and THERAVANCE and its Affiliates' interests in and to any Joint Invention Patents to make and have made API Compound and Licensed Products and to Develop and Commercialize Licensed Product, in each case (a) worldwide outside the Field (subject to the RFN) and (b) outside the Territory in the Field (subject to the China RFN).

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Section 2.02 License Grants from MYLAN to THERAVANCE. Effective only upon the existence of any MYLAN Patent and/or MYLAN Know-How, and subject to the terms of this Agreement, MYLAN hereby grants to THERAVANCE, and THERAVANCE accepts:

(a) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to conduct the Development activities for the Licensed Products in the Field in the Territory as set forth in the Development Plan in accordance with this Agreement;

(b) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to conduct the Commercialization activities for the Licensed Products in the Field in the U.S. as set forth in the Commercialization Plan in accordance with this Agreement;

(c) an exclusive license under the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Product in the Field and Commercialize Licensed Products in the Field, in each case in China (to the extent that MYLAN does not obtain exclusive rights to Develop and Commercialize Licensed Products in the Field in China pursuant to Section 2.07) and in any Reverted Countries;

(d) an exclusive license under: (i) the MYLAN Patents and MYLAN Know-How and MYLAN and its Affiliates' interests in any Joint Invention Patents solely to make and have made anywhere in the world formulated Licensed Products in the Field (including API Compound for incorporation into such Licensed Products in the Field) for purposes of Developing and Commercializing Licensed Products in the Field (A) in China (if MYLAN does not obtain exclusive rights to Develop and Commercialize Licensed Products in the Field in China pursuant to Section 2.07) and (B) in any Reverted Country(ies) and (ii) the MYLAN Patents to the extent claiming Improvements and MYLAN Know-How comprising Improvements and MYLAN and its Affiliates' interest in any Joint Invention Patents to the extent claiming Improvements solely to make and have made anywhere in the world API Compound for incorporation into Licensed Products outside of the Field for purposes of Developing and Commercializing Licensed Product outside of the Field worldwide. For such purposes and purposes of Section 14.02(b)(i)(C), "Improvements" means any and all MYLAN Inventions comprising the composition or a method of manufacture of the API Compound; and

(e) a non-exclusive license to use the Trademarks, the MYLAN Product Trademarks and MYLAN's Housemarks, in each case to the extent included on the Labeling of Licensed Products in the Field, solely for purposes of Commercializing the Licensed Products in the Field in the U.S. in accordance with the Commercialization Plan.

Notwithstanding the foregoing, MYLAN and its Affiliates retain their rights under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to (x) Develop

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and manufacture the Licensed Products in the Field for the Territory in accordance with this Agreement, (y) Commercialize the Licensed Products in the Field in accordance with this Agreement, in each case (x) and (y) including by granting Affiliates and Third Parties rights and licenses thereunder to the same extent that MYLAN is permitted to grant sublicenses under the THERAVANCE Patents and THERAVANCE Know-How as set forth in Section 2.04 and as set forth in Section 2.03(b), and (z) develop, manufacture and commercialize any other product anywhere in the world, subject to the terms and conditions of this Agreement, including Section 5.06. The exclusive licenses granted to THERAVANCE pursuant to this Section 2.02 shall be exclusive, on a Licensed Product-by-Licensed Product and Country-by-Country basis, until the earliest of (i) the expiration of the last Valid Claim within the MYLAN Patents claiming such Licensed Product in such Country, (ii) the last Valid Claim within the THERAVANCE Patents claiming such Licensed Product in such Country and (iii) the expiration of the Term, and thereafter shall be non-exclusive for the remaining portion of the Term, if any. For clarity, MYLAN retains all rights under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in the Joint Invention Patents not expressly granted herein, including all rights thereunder to develop, manufacture and commercialize products other than Licensed Products, subject to the terms and conditions of this Agreement, including Section 5.06. Notwithstanding anything herein to the contrary, the licenses granted to THERAVANCE pursuant to this Section 2.02 shall not include the right to exercise the MYLAN Patents, the MYLAN Know-How, or MYLAN and its Affiliates' interests in the Joint Invention Patents with respect any active ingredient other than TD-4208 or with respect to any delivery device that may be formulated, packaged or sold together with TD-4208 as part of a Licensed Product.

Section 2.03 Licenses to Third Parties.

(a) Without limiting MYLAN's rights under Sections 2.07 and 2.08, the licenses granted to MYLAN under Section 2.01 shall not prevent THERAVANCE from granting:

i. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Develop Licensed Products in the Territory outside the Field;

ii. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to Commercialize Licensed Products in the Territory outside the Field;

iii. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any Joint Invention Patents to make and have made API Compound and formulated Licensed Products in the Territory outside the Field; and

iv. licenses to Third Parties under the THERAVANCE Patents and THERAVANCE Know-How and THERAVANCE and its Affiliates' interests in any

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Joint Invention Patents to Develop Licensed Product outside of the Territory (other than Licensed Products in the Field for the Territory) and Commercialize Licensed Products outside of the Territory in or outside of the Field.

(b) The licenses granted to THERAVANCE under Section 2.02 shall not prevent MYLAN from granting:

i. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to Develop Licensed Products in or for the Territory in the Field;

ii. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to Commercialize Licensed Products in the Territory in the Field; and

iii. licenses to Affiliates or Third Parties under the MYLAN Patents, MYLAN Know-How and MYLAN and its Affiliates' interests in Joint Invention Patents to make and have made API Compound and formulated Licensed Products in or for the Territory in the Field.

Section 2.04 Sublicensing and Subcontracting. Either Party may sublicense or subcontract its rights to Develop, manufacture or Commercialize the Licensed Product in the Field in whole or in part to one or more of its Affiliates, provided that the rights sublicensed or subcontracted to such Affiliate shall automatically terminate if such Affiliate ceases to be an Affiliate of such Party. Each Party may also sublicense or subcontract any of its rights to Develop, manufacture or Commercialize the Licensed Product in the Field, in whole or in part, to one or more Third Parties, provided, however, that any such sublicense of Commercialization in the U.S. to be granted to a Third Party by either Party shall require the prior written consent of the other Party. Notwithstanding the foregoing, THERAVANCE shall not sublicense its rights or obligations under this Agreement to Develop the Licensed Products in the Field to a Third Party, but it may subcontract its Development responsibilities, solely in accordance with the Development Plan. Each Party shall contractually require all of its sublicensees and subcontractors to comply with all applicable terms and conditions of this Agreement, and each Party shall remain fully responsible for the compliance by such sublicensees and subcontractors with the applicable terms and conditions of this Agreement as if such sublicensees and subcontractors were such Party hereunder. Each Party shall secure appropriate covenants, obligations and rights from any such sublicensee and subcontractor to enable such Party to comply with its obligations under this Agreement, including with respect to intellectual property rights and confidentiality obligations. Without limiting the foregoing, THERAVANCE shall obligate any subcontractor of its Development responsibilities hereunder to assign all Inventions and other intellectual property rights resulting from such Development activities to THERAVANCE, so that they may be licensed to MYLAN in accordance with Section 2.01 and this Agreement. The license granted to THERAVANCE under Sections 2.02(c) and (d) shall include the right to grant sublicenses; provided that any such sublicensee shall be obligated to grant THERAVANCE a corresponding sublicensable license under any new discovery or

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technical idea related to TD-4208 or a Licensed Product after the date such sublicense is granted and any improvements to the API Compound or its manufacture, made by or on behalf of such sublicensee, and any Patents claiming such discoveries, ideas or improvements (collectively, "Sublicensee Improvements"), and THERAVANCE's rights in and to such Sublicensee Improvements shall be included in the THERAVANCE Patent Rights and THERAVANCE Know-How and subject to the licenses granted to MYLAN in Section 2.01.

Section 2.05 Trademarks and Housemarks.

(a) Trademarks. The Licensed Products in the Field shall be Commercialized in the Territory under trademarks (such trademarks, other than the Parties' Housemarks, the "Trademarks") and trade dress approved by the JSC. The Parties acknowledge and agree that the Trademarks and trade dress for the Licensed Products in the Territory in the Field under this Agreement shall be consistent with MYLAN's corporate branding and related policies. For clarity, collectively, such Trademarks and trade dress comprise the MYLAN Product Trademarks. Prior to any such proposed Trademark(s) or trade dress being submitted to the JSC, the JPC (with MYLAN taking the lead) shall be responsible for undertaking their selection. MYLAN shall exclusively own all Trademarks and all goodwill associated therewith, and shall be responsible for the procurement, filing and maintenance of trademark registrations for such Trademarks and all costs and expenses related thereto. MYLAN shall also exclusively own all trade dress and copyrights associated with the Licensed Product in the Territory in the Field. Except as provided in Section 14.02(b)(v), nothing herein shall create any ownership rights of THERAVANCE in and to the Trademarks or the copyrights and trade dress associated with the Licensed Product in the Territory in the Field, and THERAVANCE shall assign and hereby assigns to MYLAN any and all rights, title and interest in and to such Trademarks (including associated goodwill), copyrights and trade dress that may be held by THERAVANCE or its Affiliates. In the event that THERAVANCE desires to utilize the Trademarks with respect to the Commercialization of Licensed Products in the Field in China or any Reverted Country, it may provide MYLAN with notice of such desire, in which case the Parties will discuss the terms and conditions on which MYLAN would license the Trademarks to THERAVANCE for such purposes pursuant to a separate trademark license agreement.

(b) Housemarks. Each Party acknowledges the goodwill and reputation that has been associated with the other Party's Housemarks over the years, and shall use such Housemarks in a manner that maintains and promotes such goodwill and reputation and is consistent with the owner's trademark guidelines. In using the other Party's Housemarks (and, with respect to THERAVANCE, the MYLAN Product Trademarks) pursuant to the licenses granted in Sections 2.01 and 2.02 above, each Party shall (i) take reasonable precautions and actions to protect the goodwill and reputation that has inured to the other Party's Housemarks and MYLAN Product Trademarks, and (ii) refrain from doing any act that is intended, and use Diligent Efforts to refrain from doing any act that is reasonably likely, to impair the reputation of such Housemarks and MYLAN Product Trademarks.

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Section 2.06 Updates to Exhibit B. During the Term, Exhibit B shall be updated by the Parties at least quarterly to reflect any (i) additional THERAVANCE Patents first filed after the Effective Date, (ii) MYLAN Patents first filed after the Effective Date, and (iii) Joint Invention Patents first filed after the Effective Date.

Section 2.07 MYLAN Right of First Negotiation for Development and Commercialization in the Field in China. Beginning on the Effective Date and ending on [***] MYLAN shall have a first right of negotiation (the "China RFN") to enter into a mutually agreed collaboration arrangement (under this Agreement or otherwise) with THERAVANCE to pursue the Development and Commercialization of Licensed Products in the Field in China. After the Effective Date and until [***] should THERAVANCE determine to pursue Development of Licensed Products in the Field in China, itself or with a Third Party, it will provide MYLAN with written notice thereof (the "China Notice"). For clarity, if THERAVANCE determines to pursue Development of Licensed Products in the Field in China itself, it shall provide MYLAN with the China Notice prior to commencing clinical trials of the Licensed Product in the Field in or for China.

(a) Within thirty (30) days of the date on which MYLAN receives the China Notice (such date of receipt, the "China Notice Date"), MYLAN will notify THERAVANCE in writing as to whether or not it is exercising its China RFN. If MYLAN exercises its China RFN, the Parties have a further ninety (90) days to negotiate and sign a definitive agreement or a definitive amendment to this Agreement governing the Development and Commercialization of the Licensed Products in the Field in China.

(b) If MYLAN does not exercise its China RFN within thirty (30) days of the China Notice Date or if the Parties are unable, despite negotiating in good faith, to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Field in China during such ninety (90)-day period (or such longer period as the Parties may agree), THERAVANCE will be entitled to pursue all Development and Commercialization of Licensed Products in China both in and outside the Field and alone or with a Third Party and, except as expressly set forth herein, MYLAN will have no other legal or financial claim to TD-4208 in China.

Section 2.08 MYLAN Right of First Negotiation for Non-Nebulized Development and Commercialization Opportunity.

(a) If by [***] MYLAN shall have a first right of negotiation ("RFN") to enter into a mutually agreed collaboration arrangement (under this Agreement or otherwise) with THERAVANCE to pursue the Development and/or Commercialization of Licensed Product in the Non-Neb Field. Under the RFN, should THERAVANCE determine to pursue Development of Licensed Products in the Non-Neb Field itself or with a Third Party, it will provide MYLAN with written notice thereof (the "Non-Neb Notice"). For clarity, if THERAVANCE determines to pursue Development of Licensed Products in the Non-Neb Field itself, it shall provide MYLAN with the Non-Neb Notice prior to commencing clinical trials of the Licensed Product in the Non-Neb Field.

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(b) Within thirty (30) days of the date that MYLAN receives the Non-Neb Notice (such date of receipt, the "Non-Neb Notice Date"), MYLAN will notify THERAVANCE in writing as to whether or not it is exercising its RFN with respect to the Non-Neb Field. If MYLAN exercises its RFN, the Parties have a further ninety (90) days to negotiate and sign a definitive agreement or a definitive amendment to this Agreement.

(c) If MYLAN does not exercise its RFN within thirty (30) days of the Non-Neb Notice Date or if the Parties are unable, despite negotiating in good faith, to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Non-Neb Field within such ninety (90)-day period, THERAVANCE will be entitled to pursue all Development and Commercialization of Licensed Products in the Non-Neb Field on a worldwide basis alone or in combination with a Third Party and MYLAN will have no other legal or financial claim to Licensed Products in the Non-Neb Field, except as expressly set forth herein. In the event that THERAVANCE enters into an agreement granting a Third Party the right to Develop or Commercialize Licensed Product in the Non-Neb Field under Section 2.08(a) or pursuant to this Section 2.08(c), and subsequently decides to Develop Licensed Product for an indication or with respect to a territory or dosage form or delivery form within the Non-Neb Field that was not included in the rights granted to such Third Party, THERAVANCE shall provide MYLAN with notice of such decision and the RFN shall apply with respect to such indication, territory, dosage form or delivery form in the Non-Neb Field.

Section 2.09 No Other Licenses. For the avoidance of doubt, other than as expressly set forth in in this Agreement, nothing in this Agreement is intended to or shall be construed to grant either Party any rights or licenses under the intellectual property or with respect to the products of the other Party.

ARTICLE 3
GOVERNANCE OF DEVELOPMENT AND COMMERCIALIZATION OF LICENSED PRODUCT

Section 3.01 Joint Steering Committee.

(a) Purpose. The Parties hereby establish a joint steering committee (the "Joint Steering Committee" or "JSC") (i) to determine the overall strategic direction for this collaboration between the Parties and (ii) to coordinate the Parties' activities hereunder through the Term of the Agreement.

(b) Members; Officers. The JSC shall consist of up to eight (8) members, an equal number of whom shall be designated by each of MYLAN and THERAVANCE and each of whom shall be an employee of the designating Party with appropriate expertise. The initial members of the JSC are set forth on Exhibit C. Each Party's representation on

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the JSC will include individuals with responsibility for a broad range of functions important to the successful Development and Commercialization of the Licensed Product in the Field at the applicable stage in the life cycle of the Licensed Products. Each of MYLAN and THERAVANCE may replace any or all of its representatives on the JSC at any time upon written notice to the other Party. While it is expected that each JSC member attend each JSC meeting, each Party may designate a substitute to temporarily attend and perform the functions of one or more of such Party's JSC members at any meeting of the JSC. MYLAN and THERAVANCE each may, on advance written notice to the other Party, invite non-member employee representatives of such Party to attend meetings of the JSC, which invitees shall not have the right to vote in JSC decisions. The attendance of members of or any representatives to the JSC who are not employees of the applicable Party shall be subject to the prior written consent of the other Party, not to be unreasonably withheld, refused, conditioned or denied. The JSC shall be chaired on an annual rotating basis by a JSC representative of either THERAVANCE or MYLAN, as applicable, with THERAVANCE providing the first such chairperson. The Party that does not appoint the chairperson shall appoint a secretary of the JSC, who shall be a representative of such other Party and who shall serve for the same annual term as such chairperson.

(c) Responsibilities. The JSC shall perform the following functions:

i. Oversee the Development and Commercialization of the Licensed Product in the Field pursuant to the terms of this Agreement;

ii. Review and approve the Development Plan, the Development Budget, the Commercialization Plan and the Commercial Budgets, and any material amendments and annual updates to each of the foregoing, as set forth in more detail in this Agreement and subject to Section 3.01(e)(ii);

iii. At each meeting of the JSC, review actual, forecast and budgeted Net Sales for the year-to-date, as available, and for the remainder of the then-current Calendar Year;

iv. Review the progress of the JPC under the Development Plan and Commercialization Plan, including against the Development Budget and Commercial Budget, respectively;

v. Review and approve the Trademarks in accordance with Section 2.05;

vi. Review and discuss the life cycle management of, and intellectual property protection for, the Licensed Products in the Field in the Territory;

vii. Review and approve operational and other matters referred to the JSC by the JPC for decision;

viii. Review, approve, and monitor regulatory strategy and activities for the Licensed Product in the Territory in the Field in accordance with ARTICLE 7;

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ix. Review the status of all preclinical and clinical studies conducted on Licensed Products in the Territory in the Field and any results therefrom, including patient accrual to trials vs. plan;

x. Provide a forum to discuss any recall, market withdrawals or any other corrective action with respect to the Licensed Product in the Field in the Territory, in accordance with and subject to Section 7.05;

xi. Provide a forum for THERAVANCE to provide MYLAN with updates regarding the Development and Commercialization of Licensed Products outside of the Field and outside of the Territory that are reasonably likely to be material to the Development or Commercialization of Licensed Product in the Field hereunder, including material safety events or findings, updates or changes in requirements from Regulatory Authorities applicable to Licensed Product with respect to study requirements or otherwise, and timing or sites for clinical trials that may compete for enrolment with any studies included in the Development Plan, (which updates shall be provided to the JSC in a timely manner) and for the Parties to coordinate such activities with the activities under this Agreement as appropriate. For clarity, such updates shall be THERAVANCE's Confidential Information, subject to the protections of Article 9;

xii. Provide a forum for MYLAN to provide THERAVANCE with updates regarding the Development and Commercialization of a generic Competitive Product in the Field in the Territory that are reasonably likely to be material to the Development or Commercialization of Licensed Product in the Field hereunder, including with respect to timing of Regulatory Filings and timing or sites for clinical trials that may compete for enrolment with any studies anticipated or underway for Licensed Product (which updates shall be provided to the JSC in a timely manner). For clarity, such updates shall be MYLAN's Confidential Information, subject to the protections of Article 9.

xiii. In accordance with Section 3.01(f), resolve disputes or disagreements within the scope of the JSC's authority; and

xiv. Have such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

(d) Meetings. The JSC shall meet at least twice during every Calendar Year, and more frequently (i) as mutually agreed by the Parties or (ii) as required to resolve disputes, disagreements or deadlocks in the JPC, on such dates, and at such places and times, as such Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the JSC within thirty (30) days after the Effective Date. The JSC shall arrange to meet in person or convene otherwise to assess and approve, as applicable, any Development Plan or Commercialization Plan submitted to JSC in each Calendar Year so that such plans will be reviewed and approved, or objections will be submitted, in accordance with this Agreement within thirty (30) days following submission to the JSC.

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To the extent any such Development Plan or Commercialization Plan are not approved and need to be reformulated by the JPC, such plans shall be reviewed by the JSC as soon as reasonably practicable after resubmission of same, and in any event within thirty (30) days. Meetings of the JSC that are held in person shall alternate between offices of MYLAN and THERAVANCE, or such other place as the Parties may agree. Meetings the JSC may also be held by means of telecommunications or video conferences as deemed appropriate by the Parties; provided that at least one meeting of the JSC per Calendar Year shall be in person.

(e) Decision-Making.

i. The JSC may make decisions with respect to any subject matter that is subject to the JSC's decision-making authority as set forth in Section 3.01(c). All decisions of the Joint Steering Committee shall be made by Consensus, with each Party acting in good faith to reach Consensus. Prior to each JSC meeting, the JPC shall provide a list of any topics arising in the JPC that require formal review or decision-making by the JSC. Each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JSC shall not have the power to (A) amend, modify or waive compliance with this Agreement, (B) impose any financial obligation on either Party or its Affiliates or sublicensees, (C) resolve any dispute regarding the existence or amount of any sums payable under this Agreement, or (D) impose on either Party an obligation to allocate such Party or its Affiliate's tangible or intangible resources and assets in a certain manner. For clarity, the JSC shall not have the power to impose the obligations described in (B) and (D) above on a Party, including pursuant to the dispute resolution procedures set forth in Section 3.01(f).

ii. Notwithstanding anything herein to the contrary, if, in the context of the JSC's review and approval of the Commercialization Plan, THERAVANCE objects, in writing, to one or more elements of a Commercialization Plan (each, an "Objected Element"), then (A) the Parties shall use Diligent Efforts to implement all elements of such Commercialization Plan to the extent they are not Objected Elements, and (B) the Parties shall negotiate in good faith on an expedited basis, with time being of the essence, to revise the Objected Elements in a manner acceptable to the JSC as soon as practicable, including by promptly employing the dispute resolution procedures set forth in Section 3.01(f) as necessary or appropriate to reach resolution quickly. THERAVANCE shall not object to elements of the Commercialization Plan with respect to the ROW Countries unless such element is reasonably likely to have a material adverse effect on the Licensed Product either outside of the Field in the applicable ROW Country or inside the Field in the Territory.

(f) Dispute Resolution.

i. If the JSC cannot reach Consensus within thirty (30) days of the matter being brought to the JSC's attention, then such issue shall be referred to the Chief Executive Officer of THERAVANCE and the Chief Executive Officer or President of

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MYLAN (collectively, the "Officers") for resolution. The JSC will utilize all resources at its disposal, including the use of Third-Party experts, as reasonably necessary to come to Consensus and agree that the use of the Officers for resolution of any unresolved issues will be on an exceptional basis.

ii. If the Officers are unable to reach consensus within thirty (30) days of the matter being referred to them, the final decision with respect to any dispute within the scope of the JSC's decision-making authority will be made by a single, mutually acceptable Third Party arbitrator (the "Arbitrator") unless the issue is a Patent Resolution Issue (in which case it will be governed by Section 12.02(h)). Either Party can initiate such arbitration on thirty (30) calendar day's written notice to the other Party. The arbitration shall be conducted by JAMS pursuant to its Streamlined Arbitration Rules & Procedures then in effect, in New York, New York, and shall be subject to the following:

(A) Fees. The fees of associated with any such arbitration shall be shared equally by the Parties unless otherwise allocated by the Arbitrator.

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

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

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

(g) Minutes of JSC Meetings. Definitive minutes of all JSC meetings shall be finalized within thirty (30) days of the meeting to which the minutes pertain as follows:

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i. Distribution of Minutes. Within seven (7) days following a committee meeting, the secretary of the JSC shall prepare and distribute to all JSC members draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within the JSC or through the relevant dispute resolution process.

ii. Review of Minutes. The members of the JSC shall have seven (7) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of the JSC.

iii. Discussion of Comments. Upon the expiration of such second 7-day period, the Parties shall have an additional fourteen (14) days to discuss each other's comments and finalize the minutes. The secretary and chairperson of the JSC shall sign and date the final minutes. The signature of such chairperson and secretary upon the final minutes shall indicate each Party's assent to the minutes.

(h) Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate in, the JSC.

Section 3.02 Joint Product Committee.

(a) Purpose. The purpose of the Joint Product Committee shall be to prepare the Development Plan and to coordinate and monitor the implementation of the Development Plan in accordance with the Development Budget and the Commercialization Plan in accordance with the Commercial Budget.

(b) Members; Officers. Within thirty (30) days after the Effective Date, the Parties shall establish a joint product committee (the "Joint Product Committee" or "JPC"), and MYLAN and THERAVANCE shall designate an equal number of representatives, up to a maximum total of eight (8) members on such JPC, with an equal number from each Party. Each of MYLAN and THERAVANCE may replace any or all of its representatives on the JPC at any time upon written notice to the other Party. Such representatives shall be employees of the Parties who have the relevant experience and expertise to complete the activities included in the Development Plan or Commercialization Plan (as the case may be) for the Licensed Product in the Field for the next twelve months. On an occasional basis a Party may designate a substitute employee to temporarily attend and perform the functions of such Party's JPC member at any meeting of the JPC. MYLAN and THERAVANCE each may invite non-member employees representatives of such Party to attend meetings of the JPC. The attendance of members of or any representatives to the JPC who are not employees of the applicable Party shall be subject to the prior written consent of the other Party, not to be unreasonably withheld, refused, conditioned or denied. From the Effective Date until the date that is thirty (30) days after the filing of the first NDA for the Licensed Product in the Field in the U.S. the JPC shall be chaired by a representative of THERAVANCE and MYLAN shall appoint a secretary of the JPC, who shall be a representative of MYLAN. Beginning thirty (30) days after filing of the first NDA for the Licensed Product in the Field in the U.S. the JPC shall be chaired by a representative of MYLAN and

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THERAVANCE shall appoint a secretary of the JPC, who shall be a representative of THERAVANCE.

(c) Responsibilities. The JPC shall perform the following functions:

(i) Consult with THERAVANCE in the case of the Development Plan and with MYLAN in the case of the Commercialization Plan in connection with such Party's preparing and updating of the Development Plan and Commercialization Plan and their associated budgets in a timely manner (providing any comments within thirty (30) days of the submission thereof by the applicable Party) and submit them to the JSC for review and approval;

(ii) At an appropriate and regular frequency, review the Development strategy (and, when appropriate, the Commercialization strategy) for the Licensed Product in the Field;

(iii) Review and discuss whether or not to recommend to the JSC any material amendments or modifications to the Development Plan or the Commercialization Plan;

(iv) Coordinate and monitor regulatory strategy and activities for the Licensed Product in accordance with Article 7;

(v) Review and recommend to the JSC operational and other decisions for the Development of Licensed Product in the Field;

(vi) Discuss the state of the markets for Licensed Product and opportunities and issues concerning the Commercialization of the Licensed Product, including consideration of marketing and promotional strategy, marketing research plans, and labeling;

(vii) At an appropriate and regular frequency, review the status of all studies conducted on Licensed Product and any results therefrom;

(viii) At an appropriate and regular frequency, review Net Sales of Licensed Product for the year-to-date, and a current outlook for Net Sales for the remainder of the then-current Calendar Year;

(ix) Plan and review all publications described in Section 9.03, and review and approve a publications policy for such publications; and

(x) Have such other responsibilities as may be assigned to the JPC pursuant to this Agreement or as may be mutually agreed upon by the Parties through the JSC from time to time.

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(d) Meetings. The JPC shall meet at least quarterly, and more frequently as the Parties mutually agree on such dates, and at such places and times, as the Parties shall agree; provided that the Parties shall endeavor to have the first meeting of the JPC as a face to face meeting within thirty (30) days after the establishment of JPC. Meetings of the JPC that are held in person shall alternate between the offices of MYLAN and THERAVANCE, or such other place as the Parties may agree and such face to face meetings shall occur no less than twice per year. The remaining meetings may be held by means of telecommunications or video conferences as deemed appropriate.

(e) Decision-Making. The JPC may make decisions with respect to any subject matter that is subject to the JPC's decision-making authority as set forth in Section 3.02(c); provided that such decisions are consistent with the then-current Development Plan and Commercialization Plan. All decisions of the JPC shall be made by Consensus. If the JPC cannot reach Consensus within ten (10) Business Days after it has first met and attempted to reach such Consensus, the matter shall be referred on the eleventh (11th) Business Day to the JSC for resolution.

(f) Minutes of JPC Meetings. Definitive minutes of all JPC meetings shall be finalized within thirty (30) days of the meeting to which the minutes pertain as follows:

(i) Distribution of Minutes. Within seven (7) days following a committee meeting, the secretary of the JPC shall prepare and distribute to all members of such committee draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within such committee or through the relevant resolution process.

(ii) Review of Minutes. The Party members of the JPC shall have seven (7) days after receiving such draft minutes to collect comments thereon and provide them to the secretary of such committee.

(iii) Discussion of Comments. Upon the expiration of such second 7- day period, the Parties shall have an additional fourteen (14) days to discuss each other's comments and finalize the minutes. The secretary and chairperson of the JPC shall sign and date the final minutes. The signature of such chairperson and secretary upon the final minutes shall indicate each Party's assent to the minutes.

(g) Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the JPC.

(h) Sub-Committees. From time to time, the JPC may create sub-committees that will be responsible for assisting the Parties with respect to various Development, manufacturing and/or Commercialization activities undertaken pursuant to this Agreement.

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Section 3.03 General Guidelines and Initial Coordination Efforts. In all matters related to the collaboration established by this Agreement, the Parties shall strive to balance as best they can the legitimate interests and concerns of the Parties and to realize the economic potential of Licensed Product in the Field.

Section 3.04 Third Party Restrictions on Certain Activities. Prior to the Effective Date, THERAVANCE has entered into an agreement with a Third Party (which agreement has been provided to MYLAN) that restricts THERAVANCE's ability to engage in certain Development and Commercialization activities with respect to certain Combination Licensed Products (the "Restrictions"). The Parties hereby agree that prior to making any Development or Commercialization decision hereunder that may implicate the Restrictions, they will work cooperatively and in good faith to mutually agree on appropriate procedures and course of conduct (which may require, by way of example, amendment of certain provisions of this Agreement) to ensure that THERAVANCE can comply with the Restrictions in a manner which most closely approximates the purpose and economic effect of the Parties' presumed intentions hereunder.

ARTICLE 4
DEVELOPMENT

Section 4.01 Development Plan. The Parties will agree to a comprehensive development plan for Licensed Products in the Field in the Territory (the "Development Plan"), which shall be prepared by the JPC and approved by the JSC, and is designed to generate the preclinical, clinical, chemistry manufacturing and controls ("CMC"), and regulatory data and information required for filing and approval of a U.S. IND application and a U.S. NDA and the foreign equivalent applications for each ROW Country for which the JSC determines to proceed with Development of Licensed Products in the Field (as applicable). A preliminary Development Plan for the initial U.S. Development program for the Licensed Product in the Field and its associated budget will be separately agreed upon by the Parties in writing prior to or at the Effective Date (the "Preliminary Development Plan"). The Parties acknowledge that, although the Phase 3 Clinical Trial of the Licensed Product in the Field for post-acute care of COPD ("PAC Trial") is included in the documents setting forth the Preliminary Development Plan, the inclusion of the PAC Trial or any other Development activities related to post-acute care in the Development Plan to be implemented under this Agreement shall be contingent upon further refinement of the protocol, discussions with the FDA, further cost/benefit analysis and approval by the JSC. Accordingly, as of the Effective Date, THERAVANCE shall not be obligated to perform, and MYLAN shall not be obligated to pay for, the PAC Trial, and any such obligations shall be subject to the foregoing contingencies, including approval by the JSC. The full Development Plan will contain, at a minimum:

(a) a prioritized list of indications for which the Parties intend to seek Marketing Authorization for the Licensed Products in the Field, and timelines for such activities;

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(b) the configurations of Licensed Product in the Field, including Combination Licensed Product(s), that will be Developed by the Parties for the Territory, and timelines for such Development;

(c) Protocol synopses that meet the standards for registration of non-clinical, pre-clinical and clinical trials in the Countries in which the Parties intend to conduct the trials of Licensed Product in the Field that are described in such protocols;

(d) Complete study protocols, including statistical analysis plans, for the non-clinical, pre-clinical studies and clinical trials to be executed by the Parties or their representatives with respect to Licensed Products in the Field, and timelines for the conduct of each such study and trial;

(e) Regulatory strategy to coordinate submissions of Regulatory Filings, including NDAs and Marketing Authorization Applications, in each of the applicable Countries, and timelines for such submissions;

(f) Manufacturing strategy for clinical supply and transition and scale up to commercial supply for Licensed Product in the Field in the Territory, including development of a harmonized manufacturing package for registration and approval, and any bridging studies necessary in connection with a change of manufacturer for commercial supply; and

(g) A detailed Development Budget setting forth all anticipated Development Expenses by trial and Calendar Quarter.

Section 4.02 U.S. Development.

(a) Development Responsibility and Diligent Efforts. Under the direction of the JSC, THERAVANCE shall have overall responsibility for, and shall use Diligent Efforts in, the performance of all Development activities for the Licensed Product in the Field for the U.S., subject to the terms and conditions of this Agreement. THERAVANCE shall use Diligent Efforts to advance the Licensed Product in the Field through Development in the U.S. in accordance with the Development Plan. Specifically, but without limitation, THERAVANCE will be responsible for the following U.S. Development matters:

i. conducting any remaining pharmaceutical science formulation and analytical work and accompanying quality control;

ii. conducting any remaining pre-clinical and toxicology studies;

iii. conducting clinical trials required to support the first NDA for the Licensed Product in the Field, including pivotal Phase 3 Clinical Trials;

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iv. conducting all CMC work, including any activities necessary to support filing and approval of the Commercial manufacturing process, and, unless agreed by the Parties, obtaining supply of Licensed Product in the Field necessary to conduct the Development Plan for the U.S. and support filing of the first NDA for the Licensed Product in the Field;

v. preparing and filing all U.S. Regulatory Filings necessary to conduct the Development Plan, including any INDs and the first NDA for the Licensed Product in the Field, and executing any activities necessary to include in such filings to support Commercialization of the Licensed Products in the Field;

vi. leading interactions with FDA and responding to questions from FDA during review of such Regulatory Filings in accordance with Article 7; and

vii. cooperating to transition to MYLAN (or its Affiliates) activities for which MYLAN has primary responsibility with respect to Licensed Products in the Field.

(b) MYLAN Assistance. MYLAN will provide technical expertise and advice to support THERAVANCE's conduct of activities under the Development Plan, including with respect to U.S. non-clinical, preclinical and clinical trials of, and Regulatory Filings for, the Licensed Product in the Field, by reviewing and approving such Regulatory Filings in accordance with Section 7 and as otherwise set forth in the Development Plan, which assistance may be provided directly or through MYLAN's vendors or contractors and sub-contractors.

(c) Development Funding Responsibility. MYLAN shall reimburse THERAVANCE for all Development Expenses actually incurred, in accordance with the Development Budget contained in the Development Plan to Develop the Licensed Product in the Field for the U.S., from January 1, 2015 through first NDA approval for the Licensed Product in the Field in the U.S. MYLAN shall reimburse THERAVANCE on a quarterly basis in arrears for all such Development Expenses within thirty (30) days of receipt of THERAVANCE's invoice therefor. After the approval of the first NDA for the Licensed Product in the Field in the U.S., all Development Expenses incurred by THERAVANCE for the U.S. and all costs actually incurred by MYLAN in connection with the Development of the Licensed Product in the Field for the U.S. in accordance with the Development Budget contained in the then-current Development Plan approved by the JSC ("Post-Approval Development Expenses") will be Shared Expenses. For clarity, any Development Expense incurred by THERAVANCE after approval of the first NDA for the Licensed Product in the Field in the U.S. which is required or requested by FDA as a condition or in support of obtaining such NDA approval shall be Post-Approval Development Expenses.

(d) Cost Overruns. If THERAVANCE anticipates that its quarterly Development Expenses that are subject to reimbursement hereunder may exceed the corresponding portion of the Development Budget for such Calendar Quarter (a "Cost Overrun"), then, together with its monthly report set forth in Section 1.07(a)(i) of Exhibit

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F, THERAVANCE will promptly give written notice to MYLAN of the anticipated Cost Overrun, including an explanation for such Cost Overrun. Subject to this Section 4.02(c), MYLAN will reimburse THERAVANCE for Cost Overruns in a given Calendar Quarter; provided that such Cost Overrun does not cause, and is not anticipated to cause, THERAVANCE to exceed the Development Budget for such Calendar Year. If such Cost Overruns exceed the Development Budget for such Calendar Quarter by more than [***] the Parties shall, upon MYLAN's request, meet promptly to discuss the reasons for such Cost Overruns and their impact on the annual Development Budget. The Cost Overrun mechanism is implemented as a tool to monitor and effectively manage quarterly variations in Development Expenses for timing differences. It does not provide approval to increase the Development Budget. If THERAVANCE determines that projected costs for Development activities under the Development Plan will exceed the approved Development Budget for a given Calendar Year, then THERAVANCE would need to obtain approval from MYLAN to increase the Development Budget prior to incurring such costs, and the allocation of Development costs in excess of the previously approved Development Budget ("Excess Costs") will be subject to the written agreement of the Parties, not to be unreasonably withheld. If the Parties fail to agree with respect to the allocation of Excess Costs, the Parties will share any such Excess Costs equally.

(e) Development Updates. THERAVANCE shall provide MYLAN with written and oral updates regarding U.S. Development of the Licensed Product in the Field at each JPC and JSC meeting (and at least once every Calendar Quarter) at a reasonable level of detail containing at a minimum all information generated as of the date of the report that is or would be required to be included in an IND, NDA or MAA (including by way of example and not limitation: all information regarding the API Compound and formulated dosage form(s) of the Licensed Product in the Field and methods of manufacturing the same, analytical methods, batch records, pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, interim and final results from all preclinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, regulatory correspondence and data from nonclinical, preclinical and clinical studies), a summary of incurred and expected Development Expenses against the Development Budget, as well as high-level plans and objectives for the subsequent twelve (12) months.

Section 4.03 Rest of World Development.

(a) Development Responsibility. During the twenty-four (24)-month period following the Effective Date, the JSC will evaluate, on a Country-by-Country or market-by-market basis, the potential Development of the Licensed Product in the Field for Country(ies) in the ROW. Should the JSC determine to proceed with Development of the Licensed Product in the Field for any Countries in the ROW, then the Parties will use good faith efforts to determine each Party's respective responsibilities to conduct Development under a ROW Development Plan and ROW Development Budget for such Country(ies) to be agreed by the JSC. Once the Parties reach agreement on a ROW Development Plan and ROW Development Budget for a Country in the ROW, then such Country shall become a "ROW Country" for purposes of this Agreement, and each Party will use Diligent Efforts to Develop the Licensed Product in the Field in such ROW

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Country(ies) in accordance with such Development Plan and Development Budget. The Parties acknowledge and agree that, if MYLAN proposes to proceed with respect to the Development and Commercialization of Licensed Products in the Field in a particular Country in the ROW and demonstrates to the JSC that proceeding in such Country is commercially reasonable, the JSC shall not withhold its consent to proceed with the Development and Commercialization of the Licensed Products in the Field in such Country.

(b) Development Funding Responsibility. MYLAN shall pay all Development Expenses incurred or committed to and which are set forth in the Development Budget contained in the Development Plan for all ROW Development hereunder, unless otherwise agreed by the JSC as part of the Development Budget. For clarity, if THERAVANCE has responsibility to conduct any ROW Development activities under the ROW Development Plan, Section 4.02(d) shall apply with respect to ROW Development Expenses associated therewith. THERAVANCE shall reimburse MYLAN for [***] of the costs of any Licensed Product in the Field comprising Approval Batches for the ROW Countries that is not actually sold, within thirty (30) days of receipt of MYLAN's invoice therefor.

(c) Development Updates. The Parties shall provide each other with quarterly written and oral updates regarding all ROW Development of the Licensed Product in the Field at each JPC and JSC meeting (and at least once every Calendar Quarter while such Development is ongoing) at a reasonable level of detail containing at a minimum all information generated as of the date of the report that is or would be required to be included in an IND (or foreign equivalent), MAA (including by way of example and not limitation: all information regarding the API Compound and formulated dosage form(s) of the Licensed Product in the Field and methods of manufacturing the same, analytical methods, batch records, pre-formulation studies, reports summarizing development pharmaceutics, vendor information, validation documentation, interim and final results from all preclinical and clinical studies, adverse event data, patent information, regulatory documentation and filings, regulatory correspondence and data from nonclinical studies), a summary of incurred and expected Development Expenses against the Development Budget, as well as high-level plans and objectives for the subsequent twelve (12) months.

(d) Reversion of Rights. If, after an evaluation period of not less than one hundred eighty days, MYLAN's representatives to the JSC decline to proceed with Development in a particular Country in the ROW recommended by THERAVANCE, then all such rights and licenses granted to MYLAN in Section 2.01 to Develop and Commercialize the Licensed Product in such Country (each, a "Reverted Country") will revert to THERAVANCE and THERAVANCE will be free to pursue Development and Commercialization of products incorporating TD-4208 in the Field in such Reverted Country with no further obligation to MYLAN, except as expressly set forth in this Agreement.

(e) Cooperation. THERAVANCE will use Diligent Efforts to ensure that registrational studies for Licensed Products inside and outside the Field are harmonized

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with respect to design, conduct and timing to the extent reasonably required to comply with instructions and scientific advice received from Regulatory Authorities and applicable Laws. Where necessary or useful, both Parties will have access to the dossiers and documentation for the Licensed Products and other Regulatory Filings that are controlled by the other Party for the purposes of supporting Regulatory Filings for the Licensed Product in the Field in each Country where it is responsible for Development under this Agreement in accordance with Section 7.03.

(f) Compensation to MYLAN for Use of Data.

i. If: (A) MYLAN does not exercise its China RFN within thirty (30) days of the China Notice Date or if the Parties are unable to negotiate and sign a definitive agreement or a definitive amendment to this Agreement for Development and/or Commercialization of Licensed Products in the Field in China in accordance with Section 2.07; (B) THERAVANCE exercises, or permits its Affiliate or any Third Party to exercise, any right under (I) any MYLAN Patent or any manufacturing process within the MYLAN Know-How or (II) any non-clinical, pre-clinical, clinical or manufacturing data that were funded by MYLAN under this Agreement, in each case for purposes of Developing Licensed Product in the Field in China; and (C) THERAVANCE is able to Commercialize Licensed Product in the Field in China, itself or through an Affiliate or Third Party, then THERAVANCE agrees to pay to MYLAN a royalty equal to [***] of Net Sales of Licensed Product in the Field in China for the longer of the life of such MYLAN Patents and thirteen (13) years following the First Commercial Sale of Licensed Product in China.

ii. If THERAVANCE intends to incorporate, or permit its Affiliate or any Third Party to incorporate, any non-clinical, pre-clinical, clinical or manufacturing data intended to be incorporated in any Regulatory Filing in place of data that would otherwise have been required to be incorporated by or on behalf of THERAVANCE, its Affiliate or such Third Party, in each case that was funded by MYLAN under this Agreement ("Data"), in any Regulatory Filing for Licensed Products outside the Field, THERAVANCE shall promptly notify MYLAN and the Parties will negotiate in good faith a percentage [***] of the costs incurred by MYLAN to generate such Data for which THERAVANCE shall be obligated to reimburse MYLAN. Such reimbursement shall be made within thirty (30) days of THERAVANCE's receipt of MYLAN's invoice therefor, in U.S. Dollars.

iii. Notwithstanding anything herein to the contrary, THERAVANCE shall not be permitted to provide any Third Party with access to, or the benefit of, Data, either directly or through a right of use or reference pursuant to Section 7.03 or otherwise, unless such Third Party permits THERAVANCE to provide similar access, and THERAVANCE provides such access (including the right to use and incorporate into Regulatory Filings), to MYLAN with respect to data of a corresponding scope regarding Licensed Product that was funded by such Third Party, to the extent that such data exists.

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ARTICLE 5
COMMERCIALIZATION

Section 5.01 Commercialization Plan. MYLAN (in consultation with THERAVANCE through the JPC as set forth in this Section 5.01) will prepare a Commercialization Plan for Licensed Product in the Field in the Territory on an annual basis, which is designed to cover all necessary activities directed to the successful Commercialization of Licensed Product in the Field in the Territory during the following three (3) calendar years, as set forth in the Commercialization Plan Outline, and which shall reflect the bounds of operation to accomplish such objective. The Commercialization Plan should contain the depth and detail that are typical for MYLAN's internal commercial plans for similar products. A preliminary Commercialization Plan shall be prepared on or before March 31, 2016, and the Commercialization Plan shall be updated annually thereafter. Once a Commercialization Plan is developed in consultation with THERAVANCE through the JPC, MYLAN will prepare and submit a final draft of each such Commercialization Plan to the JPC for review and comment, which comments MYLAN will consider in good faith, and the JPC shall submit each Commercialization Plan to the JSC within thirty (30) days of its receipt of such final draft from MYLAN for review and approval by the JSC pursuant to Section 3.01(c)(ii).

Section 5.02 The Commercialization Plan shall contain at a minimum those elements described in the Commercialization Plan Outline, as appropriate to current knowledge at the time.

Section 5.03 U.S. Commercialization.

(a) Joint Responsibility. MYLAN and THERAVANCE shall closely collaborate, with MYLAN having primary responsibility and THERAVANCE complimenting such efforts in accordance with the agreed Commercialization Plan, with respect to, and shall use Diligent Efforts to effect, the Commercialization of the Licensed Product in the Field in the U.S. in compliance with applicable Laws and within the parameters of the then-current Commercialization Plan, all as to be set forth in more detail in the Co-Promotion Agreement. The marketing of the Licensed Product is to be planned and implemented in accordance with the Commercialization Plan that is approved by the JSC, and reviewed and monitored by the JPC. Without limiting the foregoing, the Parties will submit to the JPC representative samples of Promotional Materials from new marketing campaigns for Licensed Product in the Field in the U.S. for review and comment prior to their use in the course of their development. A division of marketing responsibilities in the U.S. between the Parties, with the intent of achieving transparency and reasonably minimizing duplication of efforts, will be defined between the Parties in the Commercialization Plan.

(b) Cost / Profit Sharing. Operating Profits (Losses) with respect to the Licensed Products in the Field in the U.S. will be shared by the Parties, sixty-five percent (65%) to MYLAN and thirty-five percent (35%) to THERAVANCE, in accordance with Section 1.03 of Exhibit F.

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(c) Co-Promotion Agreement. Within six (6) months after completion of the first Commercialization Plan pursuant to Section 5.01, the Parties shall engage in good faith negotiations to prepare and execute a definitive co-promotion agreement or similar marketing and distribution agreement describing the co-promotion activities of the Parties for such Licensed Product in the Field in the U.S. (the "Co-Promotion Agreement") consistent with the provisions of this Agreement, the terms and conditions set forth on Exhibit D, and such other terms as the Parties may agree and as are customary in an agreement of that type. The Parties shall work in good faith to ensure that the Co-Promotion Agreement is designed to be tax efficient for each Party. The Parties shall endeavor to execute such Co-Promotion Agreement as soon as possible after commencement of such negotiations and no later than eighteen (18) months prior to the anticipated First Commercial Sale of Licensed Product in the Field in the U.S.

Section 5.04 ROW Commercialization.

(a) MYLAN shall have the sole right and responsibility for, and shall use Diligent Efforts to, Commercialize Licensed Product in the Field in the ROW Countries in compliance with applicable Laws and within the parameters of the then-current Commercialization Plan.

(b) MYLAN shall bear all costs and expenses associated with the Commercialization of Licensed Product in the Field in the ROW Countries.

(c) MYLAN shall have the sole right and responsibility to distribute, sell, record sales and collect payments for Licensed Product in the Field in the ROW Countries.

(d) MYLAN shall have the sole right and responsibility for establishing and modifying the terms and conditions with respect to Commercialization of Licensed Products in the Field in the ROW Countries, including the price or prices at which Licensed Products will be sold, any discount applicable to payments or receivables, all managed care contracting issues and any other similar matters.

(e) MYLAN will be responsible for storage, order receipt, order fulfilment, shipping and invoicing of Licensed Products in the Field in the ROW Countries.

(f) If MYLAN does not use Diligent Efforts to Commercialize a Licensed Product in the Field in accordance with the Commercialization Plan for any particular ROW Country approved by the JSC, then THERAVANCE may provide MYLAN with written notice of such failure, including a description of such failure, and THERAVANCE's desire to the have the rights to Commercialize Licensed Product in the Field in such ROW Country revert to THERAVANCE. Such notice shall reference this Section 5.04(f) and Section 13.02 and shall be a notice of material breach solely with respect to such Country, triggering THERAVANCE's right to terminate this Agreement solely with respect to such ROW Country, subject to the provisions (including the cure and dispute provisions) of Section 13.02. This Section 5.04(f) sets forth

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THERAVANCE's sole remedy in the event that MYLAN fails to use Diligent Efforts to Commercialize a Licensed Product in the Field in accordance with the Commercialization Plan for any particular ROW Country; and THERAVANCE shall not have the right to terminate this Agreement in its entirety pursuant to Section 13.02 based on such failure. Any such ROW Country with respect to which this Agreement is terminated pursuant to this Section 5.04(f) due to MYLAN's failure to use Diligent Efforts shall thereafter be deemed to be a Reverted Country.

Section 5.05 Labeling.

(a) U.S. All Labeling for use with the Licensed Product in the Field in the U.S. shall include (unless prohibited by Law) the THERAVANCE Housemark and the MYLAN Housemark, each of which shall be given equal exposure and prominence on such materials (unless prohibited by Law); provided that such obligation shall apply with respect to Promotional Materials only for so long as THERAVANCE is co-promoting the Licensed Product in the Field in the U.S. In the event that THERAVANCE is not co-promoting the Licensed Product in the Field in the U.S., the Promotional Materials shall include a reference (unless prohibited by Law) to the contribution of the license from THERAVANCE for the Licensed Product (for example, by stating "Licensed from THERAVANCE BIOPHARMA R&D, INC.").

(b) ROW. All Labeling (other than Promotional Materials) for use with the Licensed Product in the Field in the ROW Countries shall include a reference (unless prohibited by Law) to the contribution of the license from THERAVANCE for the Licensed Product (for example, by stating "Licensed from THERAVANCE BIOPHARMA R&D, INC."). In addition, the THERAVANCE Housemarks and the MYLAN (or its designee's) Housemarks shall both be given exposure and prominence on such materials (unless prohibited by Law) with the THERAVANCE Housemarks being subordinate in size and prominence to the MYLAN (or its designee's) HOUSEMARKS.

Section 5.06 Commercialization Restrictions.

(a) During the Term, for so long as there is a Licensed Product in the Field being Developed or Commercialized under this Agreement in a particular country in the Territory, neither Party shall Commercialize (itself or through a Third Party) any Long Acting Muscarinic Antagonist product in the Field that is not a Licensed Product (any such product, a "Competitive Product") in such country. Further, during the Term neither Party shall Commercialize a generic Licensed Product in the Field outside of this Agreement. Notwithstanding the foregoing, MYLAN may Commercialize (itself or through an Affiliate or Third Party) a generic Competitive Product in any country in the Territory if a Third Party has launched such generic Competitive Product in such country prior to MYLAN's launch of such generic Competitive Product in such country. MYLAN will pay to THERAVANCE, during the Term, a [***] calculated in a manner [***] and payable [***]. For clarity, the foregoing shall not prevent either Party from Commercializing LAMA products in the Non-Neb Field without any obligation to the other Party. For purposes of the foregoing, a "generic" product shall mean any product that is approved based on a Marketing Authorization Application submitted pursuant to

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(a) Section 505(j) of the Federal Food Drug and Cosmetic Act or (b) an equivalent or counterpart of such section addressing approval of substitutable generics under applicable Laws in a jurisdiction outside of the U.S.

(b) Neither Party will be deemed to be in breach of the restrictions set forth in Section 5.06(a) if such Party or any of its Affiliates acquires a Competitive Product through an acquisition of or a merger with the whole or substantially the whole of the business or assets of another Person, so long as such Party (or its Affiliate) (i) enters into a definitive agreement with a Third Party to Divest such Competitive Product in the applicable Country(ies) in the Territory (other than as part of any Hold Separate Transaction) within twenty-four (24) months after the closing of such acquisition or merger, or, if such Divestiture is subject to the terms of a Hold Separate Transaction, within twelve (12) months after the closing of the acquisition or merger, or (ii) discontinues sales of the Competitive Product in the Territory no later than twelve (12) months after the closing of such acquisition or merger. "Hold Separate Transaction" means any "hold separate" transaction (whether through the establishment of a trust or otherwise) involving the proposed sale of a Competitive Product in the applicable Country(ies) in the Territory pursuant to an agreement with any Governmental Authority responsible for antitrust laws. "Divest" or "Divestiture" means, with respect to any Competitive Product, (A) the sale, exclusive license or other transfer of all of the right, title and interest in and to such Competitive Product in the applicable Country(ies) in the Territory, including all technology, intellectual property and other assets relating solely thereto, to an independent Third Party, without the retention or reservation of any rights, license or interest (other than solely an economic interest and customary residual rights in the event of a termination) in such Competitive Product with respect to the applicable Country(ies) in the Territory and (B) the shutdown of activities related to the Competitive Product in the applicable Country(ies) in the Territory such that no technology, intellectual property or other asset relating thereto is used by the applicable Party or its Affiliates and delivery of written confirmation from such Party to the other Party that the Divesting Party and its Affiliates covenant not to use any technology, intellectual property and assets solely relating to such Competitive Product in the applicable Country(ies) in the Territory during the Term.

ARTICLE 6
FINANCIAL PROVISIONS

Section 6.01 Payments. In consideration of the rights and licenses granted to MYLAN hereunder, MYLAN will pay to THERAVANCE the amounts set forth on Exhibit F.

Section 6.02 Equity Investment. Within 15 Business Days after the Effective Date, Mylan Inc. shall purchase newly issued Ordinary Shares of Theravance Biopharma, Inc. at a price per share equal to a 10% premium to the 5-day VWAP prior to announcement of this Agreement for total consideration of thirty million United States Dollars (U.S. $30,000,000). Such purchase will be made pursuant to the Share Purchase Agreement attached hereto as Exhibit G.

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Section 6.03 U.S. GAAP. All financial terms and standards used in this Agreement for sales or activities occurring in the Territory shall be determined in accordance with United States generally accepted accounting principles, consistently applied ("GAAP").

Section 6.04 Manner of Payments. All sums due under this ARTICLE 6 and Exhibit F shall be payable in United States Dollars by bank wire transfer in immediately available funds to such bank account(s) as the Party entitled to receive such payments shall designate at least five (5) Business Days in advance.

Section 6.05 Interest on Late Payments. If either Party shall fail to make a timely payment pursuant to this ARTICLE 6 and Exhibit F, any such payment that is not paid within fifteen (15) days of the date such payment is due under this Agreement shall bear interest, to the extent permitted by applicable Laws, at the average one-month London Inter-Bank Offering Rate (LIBOR) as reported on the day such payment was due in *The Wall Street Journal* (U.S. Internet version at www.wsj.com under the "Market Data" tab), plus three percent (3%) annually, 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.

Section 6.06 Tax Withholding.

(a) Any taxes, levies or other duties ("Taxes") paid or required to be withheld under the appropriate local tax laws by one of the Parties ("Withholding Party") on account of monies payable to the other Party under this Agreement shall be deducted from the amount of monies otherwise payable to the other Party under this Agreement. The Withholding Party shall secure and send to the other Party within a reasonable period of time proof of any such Taxes paid or required to be withheld by Withholding Party for the benefit of the other Party.

(b) It is contemplated that payments made to an Irish incorporated entity resident in Ireland for purposes of the U.S./Ireland Income Tax Treaty (the "Treaty") in connection with payments rendered under this Agreement will not impose a withholding obligation upon under Section 1442 of the Internal Revenue Code of 1986 as amended. THERAVANCE shall promptly provide MYLAN with Form W-8BEN-E certifying that it is the beneficial owner of the income and a resident of Ireland within the meaning of the Treaty. In the event that MYLAN concludes that it has an obligation to withhold under Section 1442 of the Code or otherwise under the Code or other applicable law with respect to any amount payable under this Agreement, MYLAN shall so notify THERAVANCE in writing, specifying the bases for such conclusion by MYLAN and the amount of Taxes and dates of any such withholding obligation that MYLAN believes it must fulfill.

(c) If MYLAN or any of its Affiliates is or becomes liable to withhold any taxes from payments made to THERAVANCE or any of its Affiliates hereunder as a result of any assignment or sublicense by MYLAN, then MYLAN shall pay to THERAVANCE an amount equal to the withholding tax MYLAN or its applicable Affiliate owes to the relevant tax authority in excess of the amounts that would have been

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owed absent such assignment or failure; provided always that if THERAVANCE is able to obtain credit for any such taxes withheld ("Creditable Taxes") against any liability to tax either in the year in which the receipt is taxable or any preceding years, THERAVANCE shall reimburse to MYLAN an amount equivalent to the Creditable Taxes. THERAVANCE shall provide MYLAN with such reasonable evidence as MYLAN may reasonably request to determine whether the taxes are creditable against taxes payable by THERAVANCE.

(d) It is understood and agreed between the Parties that any payments made by one Party to the other Party under this Agreement are exclusive of VAT, which shall be added thereon as applicable. Where VAT is properly added to a payment under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance to applicable Laws of the country in which the VAT is chargeable.

(i) In the event that THERAVANCE receives a valid VAT Form 56B (or its predecessor, 13B, until its expiration date) from MYLAN, issued in accordance with section 56 VATCA, THERAVANCE agrees that it will not apply VAT to any invoices raised to such MYLAN entities detailed within the form 56B (or 13B, if applicable) for as long as that VAT Form 56B (or 13B, if applicable) remains valid. MYLAN agrees to notify THERAVANCE immediately, should MYLAN cease to satisfy the conditions of section 56 VATCA or should the Form 56B (or 13B, if applicable) become invalid for whatever reason. In the event that MYLAN fails to produce a valid and up to date VAT Form 56B (or 13B, if applicable), VAT shall apply to any invoices from THERAVANCE as normal.

(ii) Should additional and irrecoverable VAT become payable under this Agreement as a result of any of the Parties assigning this Agreement, or any obligation hereunder to an Affiliate, the Parties agree that any such additional and irrecoverable VAT shall be borne by the assigning Party. It is agreed between the Parties that the assignment by THERAVANCE to an Affiliate in Ireland shall not come within this provision.

(iii) If additional and irrecoverable VAT is properly added to payment made under this Agreement due to no fault of either Party, including as a result of changes in applicable tax Laws the Parties will meet promptly to discuss in good faith approaches to minimising such additional and irrecoverable VAT; provided that if such VAT must be paid, the Parties will share such VAT (or any remaining portion) equally unless otherwise agreed.

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(e) To the extent a Party is required to deduct and withhold taxes on any payments to the other Party, such Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to such other Party an official tax certificate or other evidence of such withholding sufficient to enable such other Party to claim such payments of taxes. Each Party shall provide to the other Party any tax forms that may be reasonably necessary in order for such other Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall take such action as the other Party may reasonably request in order for such party not to withhold tax or to withhold tax at a reduced rate in respect of payments to be made under this Agreement to that other Party. Such action shall include but shall not be limited to, an application or submission to a Revenue Authority or other Governmental Authority seeking confirmation of an exemption, relief, published practice, concession or otherwise in respect of such withholding tax. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

Section 6.07 Currency. All amounts contained in a reports provided hereunder shall be expressed in United States Dollars and calculated from any other currency by taking the average of the daily other currency: US$ exchange rate during the Calendar Quarter used by the applicable Party to prepare its audited financial statements for external reporting purposes; provided that such method complies with GAAP and uses a widely accepted source of published exchange rates.

Section 6.08 Financial Records; Audits. Each Party shall keep, and shall cause its Affiliates and sublicensees to keep, such accurate and complete records of (i) for MYLAN, Operating Profits (Losses) and Royalties, and (ii) for THERAVANCE, Operating Profits (Losses) in the U.S., and Development Expenses in the Territory, and the calculations thereof, 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) subsequent Calendar Years to which such expenses or Net Sales 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. 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

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respect to 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 6.05, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it or overpayment made by it against payments the auditing Party is otherwise required to make to the Reporting Party under this Agreement. The documents from which were calculated the sums due under this ARTICLE 6 shall be retained by each Recording Party during the Term.

ARTICLE 7
REGULATORY MATTERS

Section 7.01 Regulatory Matters/Filings in the U.S.

(a) Pre-NDA Approval. Unless otherwise determined by the JSC or as set forth in the Development Plan, THERAVANCE shall be responsible for Regulatory Filings and interactions with Regulatory Authorities for the first Licensed Product in the Field in the U.S. up through the earlier of (i) the date that is ten (10) days after issuance of the first U.S. Marketing Authorization for the Licensed Product in the Field and (ii) the date on which the transfer of such Marketing Authorization (or the Marketing Authorization Application therefor) to MYLAN is complete (such date, the "Transfer Date"), and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Product in the Field and to seek approval of each such filing submitted for the Licensed Product in accordance with the Development Plan. Without limiting the foregoing, THERAVANCE shall submit the first NDA for the first Licensed Product in the Field to the FDA, and shall assign and transfer (and hereby assigns and transfers, effective upon the Transfer Date) such NDA and the associated Marketing Authorization to MYLAN as soon as practicable after approval, and shall use Diligent Efforts to complete such transfer on or before the date that is ten (10) days after receipt of such Marketing Authorization, in accordance with the Development Plan. Each Party shall promptly submit any and all notices and authorizations to the FDA that are necessary to effect the transfer and acceptance of such Marketing Authorization. THERAVANCE shall provide MYLAN (and its representatives) with access to all pre-clinical, clinical and manufacturing data related to the Licensed Products in the Field, including but not limited to source data and a full copy of the NDA upon transfer to MYLAN. THERAVANCE will use reasonable efforts to obtain from its manufacturer(s) of the API Compound and the Licensed Product in the Field the right for MYLAN to accompany THERAVANCE during its audits of such sites upon provision of reasonable notice or the right to provide the results of any such audit conducted by or on behalf of THERAVANCE to MYLAN, and THERAVANCE will use reasonable efforts to coordinate with MYLAN with respect to the timing of any such audits. THERAVANCE shall (to the extent legally permissible) solicit MYLAN's advice and approval of all material Regulatory Filings for the Licensed Products in the Field, material submissions and correspondence and intended discussions with the U.S. Regulatory Authorities

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regarding the Licensed Products in the Field, and shall take into account and incorporate MYLAN's reasonable comments and recommendations with respect thereto. Without limiting the foregoing and for the purpose of facilitating MYLAN's review, THERAVANCE shall submit the NDA for the first Licensed Product in the Field to MYLAN for review and comment, on a rolling basis and as soon as practicable, as individual sections are developed. THERAVANCE shall provide, and MYLAN shall have the opportunity to review, the NDA in accordance with a review process to be developed by the Parties, which process (or in the absence of agreement on a process, THERAVANCE) will ensure that MYLAN has a reasonable period to review certain sections of the NDA, including the preclinical, clinical, CMC and pharmaceutical sciences sections, and will ensure that MYLAN has a reasonable period to review and approve the full NDA prior to submission to the FDA, with the goals of providing all remaining sections of the NDA to MYLAN approximately forty-five (45) days prior to submission and allowing for prompt submission of the NDA to the FDA. In each instance, THERAVANCE shall take into account and incorporate MYLAN's reasonable comments and recommendations with respect to the NDA. The Parties shall cooperate with respect to preparing for and presenting at any meetings of any advisory committee to a Regulatory Authority regarding the Licensed Product in the Field in the U.S., provided that THERAVANCE shall have primary responsibility for leading any FDA advisory committee interactions prior to the Transfer Date. THERAVANCE shall provide to MYLAN in a timely manner (not to exceed twenty-four (24) hours after receipt or submission) copies of all material correspondence received by THERAVANCE from FDA regarding Licensed Product and of the material correspondence and submissions made by THERAVANCE to FDA regarding any Licensed Product. Without limiting the foregoing, MYLAN shall have the right to review and approve all material submissions to Regulatory Authorities regarding preclinical, clinical, CMC, manufacturing processes, or supply chain for the Licensed Product in the Field in the U.S. for which THERAVANCE is responsible for preparing and submitting prior to the Transfer Date. MYLAN shall have primary responsibility with respect to all interactions with and submissions to Regulatory Authorities regarding Promotional Materials, pricing and reimbursement for the Licensed Product in the Field in the U.S. and shall (to the extent legally permissible) solicit THERAVANCE's advice and review of all such material submissions related to the Licensed Products in the Field with the U.S. Regulatory Authorities made prior to the Transfer Date, shall take into account and incorporate THERAVANCE's reasonable comments and recommendations with respect thereto, and allow THERAVANCE to attend and participate in all meetings and scheduled calls between THERAVANCE and Regulatory Authorities regarding Promotional Materials, pricing and reimbursement for the Licensed Product in the Field the U.S. (providing THERAVANCE with reasonable advance notice of each such meeting/call). MYLAN shall also be permitted to attend and participate in all meetings and scheduled calls between THERAVANCE and Regulatory Authorities regarding the Licensed Products in the Field in the U.S., and THERAVANCE shall provide MYLAN with reasonable advance notice of each such meeting/call. With respect to Promotional Materials that MYLAN will generate during the period prior to the Transfer Date that require review and approval by FDA, THERAVANCE will facilitate the transfer of such Promotional Materials and any related correspondence to and from the FDA and MYLAN in a timely

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manner (not to exceed two (2) Business Days after receipt from MYLAN or the FDA, as applicable).

(b) Post-NDA Approval. Unless otherwise determined by the JSC or as set forth in the Development Plan, MYLAN shall be solely responsible for Regulatory Filings and interactions with Regulatory Authorities for Licensed Products in the U.S. in the Field from and after the Transfer Date, and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Products and to seek approval of each such Regulatory Filing submitted for the Licensed Products in accordance with the Development Plan and Commercialization Plan. Except as expressly set forth in Section 7.01(a), MYLAN shall hold all Marketing Authorizations and Regulatory Filings for the Licensed Products in the Field, including all information and documentation used in the Regulatory Filings relating to the Licensed Products in the Field. MYLAN shall provide THERAVANCE (and its representatives) with access to all pre-clinical, clinical and manufacturing data generated by MYLAN with respect to the Licensed Products in the Field in the U.S. as requested by THERAVANCE and reasonably necessary to exercise its Co-Commercialization rights as set forth in Article 5 and the Co-Promotion Agreement, exercise its licenses under Section 2.02 and fulfill its obligations under applicable Laws with respect thereto. MYLAN will use reasonable efforts to obtain from its manufacturer(s) of the API Compound and the Licensed Product in the Field the right for THERAVANCE to accompany MYLAN during its audits of their manufacturing sites upon provision of reasonable notice or the right to provide the results of any such audit conducted by or on behalf of MYLAN to THERAVANCE, and MYLAN will use reasonable efforts to coordinate with THERAVANCE with respect to the timing of any such audits. MYLAN shall (to the extent legally permissible and time constraints permitting) solicit THERAVANCE's advice and review of all material Regulatory Filings, material correspondence and intended discussions with the U.S. Regulatory Authorities regarding the Licensed Products in the Field (including on matters concerning pricing and reimbursement for the Licensed Product in the Field in the U.S,) and shall take into account and incorporate THERAVANCE's reasonable comments and recommendations with respect thereto. Without limiting the foregoing, MYLAN shall solicit THERAVANCE's review and approval of all Regulatory Filings of which approval is necessary to conduct clinical trials or market the Licensed Products in the Field in the U.S ("Approval Filings"). MYLAN shall provide to THERAVANCE in a timely manner copies of all material correspondence received by MYLAN from FDA regarding Licensed Product and of the material correspondence and submissions made to FDA by MYLAN regarding any Licensed Product in the Field; provided that MYLAN shall provide copies of correspondence regarding Approval Filings within twenty-four (24) hours of receipt or submission, as applicable. For clarity, MYLAN shall provide THERAVANCE with copies of Promotional Materials submitted to FDA as set forth in Section 5.03(a) and with final versions of any Promotional Materials submitted to the FDA, but shall not be obligated to provide THERAVANCE with each iteration of Promotional Materials submitted to and received from the FDA. Notwithstanding anything herein to the contrary, MYLAN shall not be responsible for, or obligated to reimburse THERAVANCE for, any costs or expenses incurred by THERAVANCE in reviewing MYLAN's Regulatory Filings or correspondence with Regulatory Authorities in the Territory, and such costs and expenses shall not be Development Expenses.

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THERAVANCE shall also be permitted to attend and participate in all meetings and scheduled calls between MYLAN and Regulatory Authorities in the U.S. regarding the Licensed Product in the Field, and MYLAN shall provide THERAVANCE with reasonable advance notice of each such meeting.

Section 7.02 Regulatory Matters/Filings in ROW Countries. Unless otherwise determined by the JSC or as set forth in the Development Plan, MYLAN shall be solely responsible for Regulatory Filings for, and interactions with Regulatory Authorities with respect to, the Licensed Products in the Field in the ROW Countries and will use Diligent Efforts to prepare and submit such Regulatory Filings for the Licensed Products and to seek approval of each such Regulatory Filing submitted for the Licensed Products in accordance with the Development Plan. MYLAN shall (to the extent legally permissible and time constraints permitting) solicit THERAVANCE's advice and review in advance of all material Regulatory Filings, material correspondence and intended discussions with any Regulatory Authority in the Territory. MYLAN shall provide to THERAVANCE in a timely manner copies of all material correspondence received from any Regulatory Authority in ROW Countries regarding any Licensed Product in the Field and of material correspondence and submissions made by MYLAN to such Regulatory Authority regarding any Licensed Product in the Field. MYLAN shall be fully responsible for bearing all its costs and expense associated with undertaking and completing said regulatory activities with respect to the Licensed Products in the Field in the ROW Countries, except that MYLAN will not be responsible for such costs and expenses for those ROW Countries that revert to THERAVANCE under Section 4.03(d) after such reversion, including but not limited to the costs of preparing, filing and prosecuting Regulatory Filings and comparable applications, fees payable in obtaining and maintaining same, responding to requests for information and additional activities from Regulatory Authorities and preparing for and presenting at any meetings of any advisory committee to a Regulatory Authority, or any other meetings requested by a Regulatory Authority. MYLAN shall not be responsible for the costs incurred by THERAVANCE in the discharge of THERAVANCE's obligations in respect of such activities or for THERAVANCE's costs relating to any ROW Country that reverts to THERAVANCE under Section 4.03(d).

Section 7.03 Reference Rights.

(a) Subject to Section 4.03(f), each Party hereby grants to the other Party (and their respective sublicensees or designees) a right of reference to Regulatory Filings owned or controlled by such Party as reasonably necessary to support the other Party's Regulatory Filings made for the following purposes: (1) for MYLAN to Develop, manufacture and Commercialize Licensed Products in the Field in the Territory in accordance with this Agreement, including conducting any bridge programs to support a change in manufacturer and (2) for THERAVANCE to (w) Develop Licensed Products in the Field in the Territory in accordance with this Agreement, (x) file the initial NDA to Commercialize the first Licensed Products in the Field in the U.S. in accordance with this Agreement, (y) Commercialize Licensed Product in the Field in the U.S. under the Co-Promotion Agreement, and (z) Develop, manufacture and Commercialize Licensed

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Products (i) in the Field in China and the Reverted Countries and (ii) outside of the Field worldwide. Such rights of reference may include:

i. the right for MYLAN to reference any and all drug master files (DMFs) referenced in the NDA for the Licensed Product in the Field in the Territory that is filed by THERAVANCE. THERAVANCE will enable right of reference to any and all such DMFs held by its contract manufacturer(s) which are relevant to Licensed Product to the extent that MYLAN elects to continue using such manufacturer for the Development or Commercialization of the Licensed Products in the Field in the Territory or as necessary to bridge to a new manufacturer. Such rights shall apply to DMFs relevant to API Compound and formulated Licensed Product, together with all updates to each of the foregoing; and

ii. the right to reference any and all trial master files (TMFs) that are relevant to Licensed Products held by each Party or any of its contract research organization(s), together with all updates to each of the foregoing.

(b) For clarity, the rights of reference set forth in Section 7.03(a)(2)(z) shall be subject to THERVANCE's reimbursement obligations under Section 4.03(f)(ii), and all rights of reference set forth in Section 7.03(a)(2) shall be subject to the limitations set forth in Section 4.03(f)(iii).

(c) Each Party granting a right of reference pursuant to this Section 7.03 shall file any notices or authorizations with Regulatory Authorities that are necessary to effect the foregoing rights of reference, at the request and expense of the other Party.

Section 7.04 Drug Safety Information. The Parties will at least 3 (three) months prior to the issuance of the first Marketing Authorization for a Licensed Product in the Field in either the U.S. or the EU, execute a pharmacovigilance agreement detailing their respective obligations for recording, investigating, summarizing, notifying, reporting and reviewing all Adverse Drug Experiences in relation to Licensed Products in the Territory in accordance with applicable Laws. Each Party shall require that its Affiliates (i) adhere to all requirements of applicable Laws which relate to the reporting and investigation of Adverse Drug Experiences, and (ii) keep the JSC apprised on a regular basis of such matters arising therefrom. For clarity, prior to the Transfer Date, THERAVANCE shall be responsible for all reporting of Adverse Drug Experiences in relation to the Licensed Product in the Field in the U.S., and on the Transfer Date such responsibilities shall transfer to MYLAN. Except as set forth in the preceding sentence or as otherwise agreed by the Parties pursuant to the pharmacovigilance agreement, MYLAN shall be responsible for managing pharmacovigilance for Licensed Products in the Field in the Territory.

Section 7.05 Recalls or Other Corrective Action. Each Party shall, as soon as practicable but in no case later than two (2) Business Days after receipt, notify the other Party of any information received by it that could reasonably form the basis for a recall, market withdrawal or other corrective action of the Licensed Products in the Field, in sufficient detail to allow the Parties to comply with any and all applicable Laws to the

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extent such level of detail is available to the reporting Party. Each Party shall promptly notify the other Party of any material actions to be taken with respect to any recall or market withdrawal or other corrective action related to Licensed Product in the Field prior to such action to permit each Party a reasonable opportunity to consult with the other Party with respect thereto, and upon the request of either Party, the Parties will endeavor to hold a JSC meeting to discuss any recall of the Licensed Product in the Field; provided that any such meeting shall not delay the initiation of any recall. All costs and expenses incurred in accordance with this Section 7.05 with respect to a recall, market withdrawal or other corrective action with respect to the Licensed Products in the Field in the U.S ("U.S. Recall Costs") shall be Shared Expenses, split between the Parties proportionate to share of the Operating Profit (Loss) to which each Party is entitled pursuant to Exhibit F, unless such recall, market withdrawal or other corrective action was solely caused by the material breach of this Agreement or the Co-Promotion Agreement, gross negligence or willful misconduct by the other Party (in which case the other Party shall pay all such costs and expenses). All costs and expenses with respect to a recall, market withdrawal or other corrective action incurred by MYLAN or its Affiliates or sublicensees with respect to Licensed Product in the Field in a ROW Country (other than a Reverted Country) ("ROW Recall Expenses" and, together with "U.S. Recall Costs", "Recall Costs) shall be borne by MYLAN unless such recall, market withdrawal or other corrective action was solely caused by the gross negligence, willful misconduct or material breach of this Agreement by THERAVANCE (in which case THERAVANCE will pay all such costs and expenses). Without limiting Section 3.01(c)(x), all final decisions with respect to any recall, market withdrawals or any other corrective action related to the Licensed Product in the Field in the Territory shall be made by MYLAN as the Marketing Authorization holder. MYLAN will keep THERAVANCE reasonably informed with respect to any recalls, market withdrawals or other corrective action with respect to the Licensed Products in the Field in the Territory and will consider any comments from THERAVANCE with respect thereto in good faith. THERAVANCE will keep MYLAN reasonably informed with respect to any recalls, market withdrawals or other corrective action with respect to the Licensed Products in the Field outside the Territory.

Section 7.06 Events Affecting Integrity or Reputation. The Parties shall notify each other promptly of any circumstances of which they are aware and which could impair the integrity and reputation of the Licensed Products in the Field in any material respect, or if a Party receives a threat from any Third Party to deliberately conduct unlawful activity in relation to the Licensed Products in the Field, which circumstances shall include, by way of illustration, tampering with or contamination of the Licensed Products in the Field by any Third Party. In any such circumstances, the Parties shall use Diligent Efforts to limit any damage to the Parties and/or to the Licensed Products in the Field in compliance with applicable Laws. The Parties shall promptly call a JSC meeting to discuss and resolve such circumstances.

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ARTICLE 8
ORDERS, MANUFACTURE AND SUPPLY

Section 8.01 Orders and Terms of Sale.

(a) U.S. In the U.S., MYLAN will have responsibility, subject to the Co-Promotion Agreement and the parameters established by the JSC in the Commercialization Plan, for establishing and modifying the commercial terms and conditions with respect to the sale and distribution of Licensed Product in the Field, including matters such as the price at which the Licensed Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed. In the U.S., subject to the other terms of this Agreement, MYLAN shall have the sole right to (i) receive, accept and fill orders for Licensed Products in the Field, (ii) control invoicing, order processing and collection of accounts receivable for sales of Licensed Products in the Field, and (iii) record sales of Licensed Products in the Field in its books of account.

(b) ROW Countries. In the ROW Countries, MYLAN shall have the sole right to (i) receive, accept and fill orders for Licensed Products in the Field, (ii) control invoicing, order processing and collection of accounts receivable for sales of Licensed Products in the Field, (iii) record sales of Licensed Products in the Field in its books of account, and (iv) establish and modify the commercial terms and conditions with respect to the sale and distribution of Licensed Products in the Field, including matters such as the price at which the Licensed Products will be sold and whether any discounts, rebates or other deductions should be made, paid or allowed.

Section 8.02 Supply of API Compound and Formulated Licensed Product.

(a) Selection of Manufacturer. The Parties shall mutually agree (through the JSC) to the selection of an appropriate source(s) for manufacture and supply of API Compound and formulated Licensed Product in the Field to support Phase 3 Clinical Trials and commercial launch in the Territory, in accordance with this Section 8.02(a). Such manufacturer(s) shall be compliant with cGMP, applicable Laws, appropriate U.S. quality and regulatory standards, and similar requirements in the EU. MYLAN shall have the right to identify the manufacturer for Commercial supply of API Compound and formulated Licensed Product in the Field for the Territory, which may be a MYLAN Affiliate, and submit such manufacturer(s) to the JSC for approval, subject to Exhibit I. THERAVANCE shall have the right to identify the Third Party manufacturer for supply of formulated Licensed Product for Phase 3 Clinical Trials included in the Preliminary Development Plan, and submit such manufacturer(s) to the JSC for approval; subject to Exhibit I. Unless otherwise agreed by the Parties, THERAVANCE shall be responsible for procuring supply of Licensed Product in the Field to support such Phase 3 Clinical Trials from such Third Party manufacturer. Subject to the foregoing sentence, MYLAN shall be responsible for manufacture of API Compound for incorporation into Licensed Product in the Field and formulated Licensed Product in the Field for Development and Commercialization in the Territory, by itself or through one or more Third Parties.

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(b) Transition Assistance. THERAVANCE and its Third Party manufacturers will work actively and collaboratively with MYLAN to assist MYLAN in assuming such manufacturing responsibilities on a timely basis. Promptly after identifying the source of API Compound or formulated Licensed Product in the Field for commercial launch in the Territory, THERAVANCE shall provide MYLAN with a Technology Transfer Package and all reasonable cooperation and assistance to achieve technology transfer of the current manufacturing processes for TD-4208, API Compound and formulated Licensed Product in the Field (including the following processes: manufacturing, analytical methods, release procedures and all other relevant processes). THERAVANCE shall use Diligent Efforts as and to the extent reasonably requested by MYLAN to assist MYLAN at its option to (i) take assignment of THERAVANCE's existing Licensed Product, API Compound or component supply agreements, (ii) negotiate new agreements with THERAVANCE's existing suppliers, and/or (iii) enter into three-way agreements among THERAVANCE, MYLAN, and such suppliers for the transitional period, if required. THERAVANCE's assistance under the foregoing paragraph shall be at no additional charge to MYLAN.

ARTICLE 9
CONFIDENTIAL INFORMATION

Section 9.01 Confidential Information. Each of MYLAN and THERAVANCE shall treat all Confidential Information received from the other Party with the same degree of care it uses to maintain the confidentiality of its own Confidential Information, but in no event less than a reasonable degree of care. Neither Party shall use the Confidential Information of the other Party for any purpose other than to exercise its rights and fulfill its obligations under this Agreement, including (a) preparing, filing, prosecuting and maintaining Patents in accordance with this Agreement, (b) prosecuting and defending litigation, and (c) making Regulatory Filings or communicating with Regulatory Authorities in accordance with this Agreement. Neither Party shall disclose the same to any other Person other than to Third Parties as reasonably necessary to conduct the foregoing activities and to such of its Affiliates, employees, contractors, advisors, counsel or agents (collectively, "Representatives") who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement. A Receiving Party shall advise any such Person who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure that all such Representatives comply with such obligations as if they had been a Party hereto and shall be liable breach of this Article 9 caused by such Representatives use or disclosure of Confidential Information disclosed to it by such Receiving Party. Except as otherwise provided in Article 14, upon termination of this Agreement, the Receiving Party shall destroy all documents containing, and erase from tapes or other media, the Confidential Information of the Disclosing Party that remain in the Receiving Party's or its agents' possession and provide the Disclosing Party with a certificate of such destruction, except that (A) the Receiving Party shall not be obligated to destroy such documents, tapes or media in the possession of its Board of Directors; and (B) the Receiving Party may keep

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one copy of the Confidential Information under the control of the legal department of the Receiving Party solely for (i) archival purposes, (ii) ascertaining any continuing obligations hereunder, or (iii) enforcing its rights hereunder. Notwithstanding the foregoing, the Receiving Party also shall be permitted to retain such additional copies of or any computer records or files containing the Confidential Information of the Disclosing Party that have been created solely by the Receiving Party's automatic electronic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose. Any retained copy of Confidential Information shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this ARTICLE 9.

Section 9.02 Permitted Disclosure and Use.

(a) Notwithstanding Section 9.01, a Party may disclose this Agreement or Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to: (i) during the Term, obtain Marketing Authorization of Licensed Product; (ii) enforce the provisions of this Agreement; or (iii) comply with applicable Law. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 9.02(a)(i) or (iii), such Party shall (to the extent permitted by applicable Law) give reasonable advance notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information. The Receiving Party will cooperate reasonably with the Disclosing Party's efforts to protect the confidentiality of the information.

(b) Each Party acknowledges that from time-to-time during the Term the other Party may have a legitimate business need to make a disclosure to a Third Party of Confidential Information in connection with the Development, manufacture or Commercialization of Licensed Product (including, (i) in the case of THERAVANCE, in connection with due diligence or negotiation for an out- license related to the Licensed Product outside the Field or in China, or (ii) in the case of MYLAN, in connection with due diligence or negotiation in connection with a potential Commercialization partner in a ROW Country or a manufacturing source). The Parties agree that in such cases, Confidential Information may be disclosed to such Third Party(ies) for the legitimate business need provided that a customary and reasonable legally binding confidentiality and non-use agreement ("CDA") is entered into with such Third Party that is at least as protective of such Confidential Information as this Article 9.

Section 9.03 Publications. Each Party shall submit to the JPC for review and approval all proposed academic, scientific and medical publications and public presentations relating to a Licensed Product or any Development activities under this Agreement for review in connection with preservation of related patent rights, and trade secrets to determine whether Confidential Information should be modified or deleted from the proposed publication or public presentation and to ensure compliance with the publications policy adopted by the JPC and approved by the JSC (the "Publications Policy"). Written copies of such proposed publications and presentations shall be

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submitted to the JPC no later than ninety (90) days before submission for publication or presentation and the JPC shall provide its comments with respect to such publications and presentations within thirty (30) days of its receipt of such written copy. The review period may be extended for an additional sixty (60) days if a representative of the non-publishing Party on the JPC can demonstrate a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. By mutual agreement of the Parties, this period may be further extended.

Section 9.04 Public Announcements. Except as may be expressly permitted under Section 9.03 or required by applicable Laws and subject to the final three sentences of this Section 9.04, neither Party will make any public announcement of any information regarding this Agreement or the terms hereof, the Licensed Product in the Field or any Development or Commercialization activities conducted under this Agreement (the "Public Announcement Matters") without the prior written approval of the other Party, which approval shall not be conditioned, delayed, refused or withheld unreasonably; provided however, that neither Party shall be prevented from complying with any duty of disclosure that it may have pursuant to applicable Laws or the rules of any recognized stock exchange so long as the Disclosing Party provides the other Party at least five (5) Business Days prior written notice of such disclosure to the extent practicable and only discloses information to the extent required by applicable Laws or the rules of any recognized stock exchange. Once any statement is approved for disclosure by the Parties or information is otherwise made public in accordance with the preceding sentence, either Party may make a subsequent public disclosure of the contents of such statement without further approval of the other Party. Notwithstanding anything herein to the contrary, MYLAN may inform its customers, suppliers and business contacts of the licensing of the Licensed Products in the Field hereunder in the ordinary course of business. In its press releases and public filings that mention or are regarding any Licensed Product in the Field, MYLAN shall refer to the fact that it has licensed the Licensed Product(s) from THERAVANCE, and THERAVANCE shall refer to the fact that it has licensed the Licensed Product(s) to MYLAN in its press releases and public filings. Within sixty (60) days of the Effective Date, appropriate representatives of the Parties will decide a process and principles for reaching timely consensus on how the Parties will make public disclosure concerning Public Announcement Matters. Notwithstanding the foregoing, but subject to Sections 2.07 and 2.08, respectively, THERAVANCE shall not be required to obtain the prior written approval of MYLAN for any public announcement relating to TD-4208 or Licensed Product in connection with or related to use or intended use in China or outside the Field; provided that such announcement would not reasonably be expected to have a material adverse impact on the Parties activities with respect to the Licensed Product in the Field hereunder.

Section 9.05 Confidentiality of This Agreement. The terms of this Agreement shall be Confidential Information of each Party and, as such, shall be subject to the provisions of this ARTICLE 9.

Section 9.06 Termination Of Prior Confidentiality Agreement. This Agreement supersedes the Confidentiality Agreement between MYLAN and Theravance Biopharma

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US, Inc. dated June 2, 2014. The information exchanged under such agreement shall be deemed to have been exchanged under this Agreement.

Section 9.07 Survival. The obligations and prohibitions contained in this ARTICLE 9 shall survive for a period of five (5) years after the expiration or termination of this Agreement.

ARTICLE 10
WARRANTIES; COVENANTS

Section 10.01 Mutual Warranties. THERAVANCE and MYLAN each warrants to the other as of the Effective Date that:

(a) Such Party (i) is a company duly organized, validly existing, and in good standing under the applicable Laws of the jurisdiction of its incorporation; (ii) is duly qualified as a corporation and in good standing under the Laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification, or where the failure to be so qualified would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder or MYLAN's ability to Commercialize the Licensed Products in the Field in the Territory in accordance with this Agreement; (iii) has the requisite corporate power and authority and the legal right to conduct its business as conducted as of the Effective Date and currently contemplated to be conducted pursuant to this Agreement; (iv) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over such Party, to the extent required for the ownership and operation of its business and the performance of its obligations hereunder, where the failure to obtain such licenses, permits, consents or approvals, or to make such notices would have a material adverse effect on its financial condition or its ability to perform its obligations hereunder or MYLAN's ability to Commercialize the Licensed Products in the Field in the Territory; and (v) is in compliance with its charter documents;

(b) The execution, delivery and performance of this Agreement by such Party and all instruments and documents to be delivered by such Party hereunder (a) are within the corporate power of such Party; (b) have been duly authorized by all necessary or proper corporate action; (c) do not conflict with any provision of the charter documents of such Party; (d) will not, to the best of such Party's knowledge, violate applicable Laws or any order or decree of any court or Governmental Authority; (e) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which such Party is a Party, or by which such Party or any of its property is bound;

(c) This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by

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applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies; and

(d) All of its employees and consultants conducting activities under this Agreement have executed agreements or have existing obligations under applicable Laws requiring assignment to such Party of all Inventions made by such individuals during the course of and as the result of their association with such Party, and obligating such individuals to maintain as confidential such Party's Confidential Information.

Section 10.02 Debarment. MYLAN and THERAVANCE each represents and warrants to the other, and (as applicable) covenants, that neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates has used or will use in any capacity, in connection with the Development of the Licensed Products or the performance of this Agreement, any Person who has been debarred pursuant to Section 306 of the U.S. Federal Food Drug and Cosmetic Act, or who is the subject of a conviction described in such section. Each Party agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

Section 10.03 Additional THERAVANCE Warranties. THERAVANCE, on behalf of itself and all of its Affiliates, further warrants to MYLAN as of the Effective Date that:

(a) an accurate and complete list of all THERAVANCE Patents are set forth in Exhibit B under "THERAVANCE Patents";

(b) it or its Affiliate, Theravance Biopharma R&D IP LLC, is the sole and exclusive owner of all right, title and interest in and to the THERAVANCE Patents listed in Exhibit B and the THERAVANCE Know-How, all of which are owned free and clear of any liens, charges and encumbrances;

(c) THERAVANCE has the right to grant MYLAN the licenses under the THERAVANCE Patents and THERAVANCE Know-How set forth in Section 2.01 free and clear of any liens, charges and encumbrances;

(d) to THERAVANCE's knowledge, the manufacture, use and sale of the forms of TD-4208 and the Licensed Product in the Field that exist as of the Effective Date do not infringe upon any intellectual property rights of any Third Party;

(e) there are no claims, judgments or settlements against or owed by THERAVANCE or any of its Affiliates relating to THERAVANCE Patents or THERAVANCE Know-How, TD-4208 or the Licensed Products or any past, pending or, to THERAVANCE's knowledge, threatened, claims or litigation relating to THERAVANCE Patents or THERAVANCE Know-How, TD-4208 or the Licensed Products, including any such claims or litigation that alleges that the Development,

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manufacture, use or Commercialization of the Licensed Product infringes, misappropriates or otherwise violates the intellectual property rights of a Third Party;

(f) There is no litigation pending or threatened by THERAVANCE alleging that a Third Party is or was infringing, misappropriating, or otherwise violating the THERAVANCE Patents, and there has been no such litigation in the past;

(g) there are no Patents or know-how, other than THERAVANCE Patents or THERAVANCE Know-How, owned or licensed by THERAVANCE or its Affiliates that claim or cover the Development, manufacture or Commercialization of TD-4208 or the Licensed Products in the Field; provided that if THERAVANCE subsequently identifies any such Patents or Know-How they shall automatically be included in the definition of THERAVANCE Patents or THERAVANCE Know-How, as applicable

(h) there are no interferences, re-examination or re-issue proceeding(s) pending, declared or, to THERAVANCE's knowledge, threatened involving THERAVANCE with the THERAVANCE Patents, nor any re-examination or reissue proceeding concerning such THERAVANCE Patents and, to THERAVANCE's knowledge, the THERAVANCE Patents are valid and enforceable;

(i) there are no actual or pending, and to THERAVANCE's knowledge, no alleged or threatened, adverse actions, suits, claims, or formal governmental investigations, or settlements or judgments, involving TD-4208 or Licensed Product by or against THERAVANCE or any of its Affiliates in or before any governmental authority. In particular, to its knowledge, there is no pending or threatened product liability action involving the use or administration of a Licensed Product;

(j) all preclinical and clinical trials of Product that have been conducted by or on behalf of THERAVANCE that have been submitted to any Regulatory Authority in connection with any Licensed Product, have been conducted in compliance in all material respects with applicable Law, including good clinical practices and good laboratory practices, as applicable;

(k) all Regulatory Filings that have been submitted to a Regulatory Authority by or on behalf of THERAVANCE with respect to Licensed Product were complete and accurate in all material respects on the date filed or furnished (or were corrected in or supplemented by a subsequent filing);

(l) THERAVANCE has disclosed in writing to MYLAN all currently effective and material agreements relating to TD-4208 or the Licensed Products to which THERAVANCE and/or any of its Affiliates is a party as of the Effective Date (excluding clinical site agreements, clinical investigator agreements and related documentation, and excluding confidentiality or non-disclosure agreements with Third Parties);

(m) THERAVANCE is not a Party to any in-effect agreement or obliged to any surviving obligation under any expired agreement, in each case pursuant to which THERAVANCE has licensed to a Person rights under the THERAVANCE Patents, THERAVANCE Know-How, or Joint Invention Patents to Develop or Commercialize

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the Licensed Product in the Field in the Territory or that would otherwise limit THERAVANCE's ability to grant MYLAN a license of the scope set forth in Section 2.01, and THERAVANCE will not enter into any such Agreement during the Term; and

(n) the Restrictions shall not limit MYLAN's Development and Commercialization activities within the scope of the licenses granted to it pursuant to Section 2.01.

Section 10.04 Covenants.

(a) Each Party hereby covenants and agrees during the Term that it shall carry out its obligations or activities hereunder in accordance with (i) the terms of this Agreement and (ii) all applicable Laws.

(b) THERAVANCE hereby covenants and agrees that it will not expand the scope of, or otherwise modify, the Restrictions in a manner that will impair the Parties' ability to Develop, manufacture or Commercialize the Licensed Products pursuant to this Agreement without the prior written consent of MYLAN.

Section 10.05 Disclaimer of Warranty. Subject to the specific warranties and representations given under Section 10.01 through and including Section 10.03, nothing in this Agreement shall be construed as a warranty or representation by either Party with respect to the subject matter of this Agreement, including any such warranty or representation (i) that any Licensed Product made, used, sold or otherwise disposed of under this Agreement is or will be free from infringement of Patents, copyrights, trademarks, industrial design or other intellectual property rights of any Third Party, (ii) regarding the effectiveness, value, safety, non-toxicity, patentability, or non-infringement of any patent technology, TD-4208, Licensed Product or any information or results provided by either Party pursuant to this Agreement or (iii) that any Licensed Product will obtain Marketing Authorization. EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT EACH OF THERAVANCE AND MYLAN EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKE NO EXPRESS OR IMPLIED WARRANTY, STATUTORY OR OTHERWISE, OF ANY KIND, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE REGARDING TD-4208, LICENSED PRODUCT, THERAVANCE CONFIDENTIAL INFORMATION, MYLAN CONFIDENTIAL INFORMATION, THERAVANCE PATENTS AND THERAVANCE KNOW-HOW OR MYLAN PATENTS AND MYLAN KNOW-HOW.

Section 10.06 Anti-Corruption Laws.

(a) 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 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

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

(b) Without limiting any other provision in this Section 10.06, 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 but not limited to the FCPA, and such investigation, or such failure, would reasonably be expected to adversely impact in any significant manner the Commercialization of the Licensed Product in the Field in the Territory.

(c) Each Party warrants that all Persons acting on its behalf will comply with all applicable Laws in connection with all work conducted hereunder, including but not limited to the Anti-Corruption Laws if any, prevailing in the country(ies) in which it has its principal places of business or performs work hereunder.

(d) Each Party further warrants and represents that should it learn or have reason to suspect any breach of its covenants in this Section 10.06, it will immediately notify the other Party.

(e) 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 10.6. 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.

Section 10.07 Trade Control Laws.

(a) Each Party will fully comply with all applicable export control, economic sanctions laws and anti-boycott regulations of the United States of America and other governments, including but not limited to 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").

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

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(c) No API Compound or Licensed 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.

(d) 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.

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

(f) Each Party shall commit to maintaining awareness of the importance of Trade Control Laws throughout its organization. Each Party shall take such actions as are necessary and reasonable to prevent API Compound and Licensed 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.

(g) Each Party will keep accurate and consistent records 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.

ARTICLE 11
INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

Section 11.01 Indemnification by MYLAN. Subject to Section 11.04, MYLAN shall defend, indemnify and hold harmless THERAVANCE, its Affiliates and its and their officers, directors, stockholders, employees, successors and assigns (each, a "THERAVANCE Indemnitee") from and against all Losses resulting from Claims brought by Third Parties against a THERAVANCE Indemnitee to the extent such Claims arise out of (a) MYLAN's or its Affiliates' negligence or willful misconduct in performing any of their obligations, or exercising any of their rights, under this Agreement, (b) a breach by MYLAN (or its Affiliates) of any of their representations, warranties, covenants or agreements under this Agreement, or (c) except to the extent resulting from the activities listed in Section 11.02(c), the Development, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Product by MYLAN, its Affiliates, agents, sublicensees or distributors, except in each case to the extent such Claims or Losses result from (x) the negligence or willful misconduct of THERAVANCE or its Affiliates or the breach by THERAVANCE or its

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Affiliates of any obligation under this Agreement or (y) the manufacture of the API Compound or Licensed Product by MYLAN or its Affiliate's Third Party manufacturer and MYLAN is not indemnified by such Third Party for such Claims or Losses.

Section 11.02 Indemnification by THERAVANCE. Subject to Section 11.04, THERAVANCE shall defend, indemnify and hold harmless MYLAN, its Affiliates and its and their officers, directors, stockholders, employees, successors and assigns (each, a "MYLAN Indemnitee") from and against all Loss resulting from Claims brought by Third Parties against a MYLAN Indemnitee to the extent such Claims arise out of (a) THERAVANCE's or its Affiliates' negligence or willful misconduct in performing any of their obligations, or exercising any of their rights, under this Agreement, (b) a breach by THERAVANCE (or its Affiliates) of any of their representations, warranties, covenants or agreements under this Agreement, or (c) the Development, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Product by THERAVANCE, its Affiliates, agents, sublicensees or distributors, except in each case to the extent such Claims or Losses result from (x) the negligence or willful misconduct of MYLAN or its Affiliates or the breach by MYLAN or its Affiliates of any obligation under this Agreement or (y) the manufacture of the API Compound or Licensed Product by THERAVANCE or its Affiliate's Third Party manufacturer and THERAVANCE is not indemnified by such Third Party for such Claims or Losses.

Section 11.03 Procedure for Indemnification.

(a) Notice. Each Party will notify promptly the other in writing if it becomes aware of a Claim (actual or potential) by any Third Party (a "Third Party Claim") for which indemnification may be sought by that Party (the "Indemnified Party") and will give all information in its possession with respect thereto to the other Party (the "Indemnifying Party"). The Indemnified Party shall not make any admission or statement concerning such Third Party Claim. The Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Third Party Claims. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party without the consent of the Indemnifying Party or any failure by such Party to notify the Indemnifying Party of the Claim materially prejudices the defense of such Claim.

(b) Defense of Claim. The Indemnifying Party shall have the right to control the defense of a Third Party Claim, provided it gives notice to the Indemnified Party of its intention to do so within forty-five (45) days after the receipt of the written notice from the Indemnified Party of the potentially indemnifiable Third Party Claim (the "Litigation Condition"). Subject to compliance with the Litigation Condition, the Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Parties in the defense or settlement of such Third Party Claim and shall pay the fees and costs of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnified Party shall not settle any Third Party Claim for which it is seeking indemnification without the

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prior written consent of the Indemnifying Party. The Indemnified Party shall, if requested by the Indemnifying Party, cooperate in all reasonable respects in the defense of such Claim that is being managed and/or controlled by the Indemnifying Party, at the expense of the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of such Third Party Claim, unless such settlement includes an unconditional release of the Indemnified Party from all liability to Third Parties with respect to such Third Party Claim.

Section 11.04 Assumption of Defense. Notwithstanding anything to the contrary contained herein, an Indemnified Party shall be entitled to assume its own defense against any Third Party Claim upon written notice to the Indemnifying Party, in which case the Indemnifying Party shall be relieved of liability under Section 11.01 or Section 11.02, as applicable, solely for such Third Party Claim and related Losses, if it had previously satisfied the Litigation Condition.

Section 11.05 Insurance.

(a) During the Term of this Agreement and for a period of five (5) years after the termination or expiration of this Agreement, MYLAN shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts which are reasonable and customary in the pharmaceutical industry for companies of comparable size in the territories where MYLAN has activities, taking into account the nature of those activities. Such product liability insurance or self-insured arrangements shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Licensed Products in the Field by or on behalf of MYLAN in the Territory. MYLAN shall provide written proof of the existence of such insurance to THERAVANCE upon request.

(b) During the Term of this Agreement and for a period of five (5) years after the termination or expiration of this Agreement, THERAVANCE shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such product liability insurance or self-insured arrangements shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Licensed Product worldwide in and outside of the Field by or on behalf of THERAVANCE. THERAVANCE shall provide written proof of the existence of such insurance to MYLAN upon request.

(c) Without limiting the foregoing, each Party shall at a minimum maintain a product liability insurance policy with a [***] limit in the aggregate. For clarity, MYLAN shall have the right to provide the total limits required under this Section 11.05 by any combination of primary and umbrella/excess coverage and may provide all or part of the required coverage through its insurance captive.

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Section 11.06 Limitation of Liability.

(a) Consequential Damages Waiver. EXCEPT FOR A BREACH OF ARTICLE 9 OR WITH RESPECT TO INDEMNIFICATION OBLIGATIONS ARISING UNDER THIS ARTICLE 11, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

(b) Liability Cap. EXCEPT FOR (a) ANY AMOUNTS PAYABLE BY MYLAN TO A THIRD PARTY PURSUANT TO MYLAN'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 11 OR (b) WILLFUL MISCONDUCT OR FRAUD BY MYLAN OR ITS AFFILIATES, FOR WHICH THERE SHALL BE NO CAP ON AVAILABLE DAMAGES OR OTHERWISE, IN NO EVENT SHALL MYLAN'S LIABILITY FOR DAMAGES UNDER THIS AGREEMENT EXCEED, IN THE AGGREGATE, [***] REGARDLESS OF WHETHER MYLAN HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

ARTICLE 12
PATENTS AND INVENTIONS

Section 12.01 Inventions.

(a) Disclosure and Determination of Inventorship. Each Party shall promptly disclose to the other Party in writing any Inventions made by it during the Term. The determination of inventorship for such Inventions shall be made in accordance with the patent Laws in the U.S.

(b) Ownership of Inventions. THERAVANCE shall own all THERAVANCE Inventions and MYLAN shall own all MYLAN Inventions. All Joint Inventions shall be owned jointly by THERAVANCE and MYLAN. Subject to the rights and licenses granted hereunder, each Party may license and otherwise exploit the Joint Inventions and Joint Invention Patents without the consent of, or reporting or accounting to, the other Party and each Party hereby waives any right it may have under the Laws of any jurisdiction to require any such consent, reporting or accounting.

Section 12.02 Preparation, Prosecution and Maintenance of Patents.

(a) Preparation, Prosecution and Maintenance of THERAVANCE Patents.

i. Responsibility. THERAVANCE shall have the first right, and the obligation to prepare, file and prosecute in a diligent manner (including by conducting interferences, oppositions and reexaminations or other similar proceedings), and maintain

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(by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and (subject to Section 12.02(f)) extend all THERAVANCE Patents, in accordance with input from MYLAN as provided herein. THERAVANCE may elect not to prepare, file, prosecute, or maintain THERAVANCE Patents subject to the provisions of Section 12.02(d).

ii. Abandonment. THERAVANCE shall consult with MYLAN and comply with Section 12.02(d) prior to abandoning any THERAVANCE Patents in the Territory.

iii. Input. THERAVANCE shall regularly advise MYLAN of the status of all THERAVANCE Patents in the Territory, and shall provide MYLAN with copies of all material documentation concerning THERAVANCE Patents in the Territory, including all correspondence to and from any Governmental Authority. Prior to filing new THERAVANCE Patents, including patent applications claiming THERAVANCE Inventions, or significant prosecution documents relating to THERAVANCE Patents in the Territory, THERAVANCE shall solicit MYLAN's advice on the content of the patent application or prosecution document and THERAVANCE shall take into account and incorporate MYLAN's reasonable comments related thereto, unless (without fault of THERAVANCE) deadlines will not permit such review or MYLAN notifies THERAVANCE that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, THERAVANCE shall have the final decision-making authority with respect to any action relating to Patents claiming THERAVANCE Inventions or THERAVANCE Patents, subject to the provisions of Section 12.02(d) or Section 12.02(h), although THERAVANCE and MYLAN shall seek to agree on which Countries in the Territory in which THERAVANCE Patents shall be filed and the content of patent applications or prosecution documents.

iv. Expenses. Subject to a budget to be mutually agreed upon by the Parties and updated periodically, MYLAN will reimburse [***] of THERAVANCE's actual out-of-pocket expenses incurred after the Effective Date in filing, prosecution and maintenance of THERAVANCE Patents in the Territory. THERAVANCE shall be responsible for all of THERAVANCE's other expenses relating to THERAVANCE Patents.

(b) Preparation, Prosecution and Maintenance of MYLAN Patents.

i. Responsibility. MYLAN shall have the exclusive right, but not the obligation, to prepare, file, prosecute, maintain and extend MYLAN Patents. MYLAN may elect not to prepare, file, prosecute, maintain or extend MYLAN Patents, subject to Section 12.02(e) solely with respect to the MYLAN Patents that claim solely the Licensed Products in the Field, including the composition, manufacture or use thereof (such MYLAN Patents, the "MYLAN Product Patents").

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ii. Status. MYLAN shall keep THERAVANCE reasonably informed with respect to the status of the MYLAN Patents and shall consult with THERAVANCE and comply with Section 12.02(e) prior to abandoning any MYLAN Product Patent.

iii. Input. MYLAN shall regularly advise THERAVANCE of the status of all MYLAN Product Patents and, at THERAVANCE's request, shall provide THERAVANCE with copies of all documentation concerning MYLAN Product Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications or significant prosecution documents relating to MYLAN Product Patents, MYLAN shall solicit THERAVANCE's advice on the content of the patent application or prosecution document and MYLAN shall take into account THERAVANCE's reasonable comments related thereto, unless (without fault of MYLAN) deadlines will not permit such review or THERAVANCE notifies MYLAN that it does not wish to review such documents. In the event of a dispute between the Parties regarding the content of patent applications or prosecution documents, MYLAN shall have the final decision-making authority with respect to any action relating to MYLAN Product Patents subject to the provisions of Section 12.02(e) or Section 12.02(h), although THERAVANCE and MYLAN shall seek to agree on which Countries in the Territory in which MYLAN Product Patents shall be filed within the priority period and the content of patent applications or prosecution documents with respect to the MYLAN Product Patents.

iv. Expenses. MYLAN shall be responsible for all of MYLAN's expenses incurred to procure MYLAN Patents in the Territory, including all filing fees, translations, maintenance, annuities, and protest proceedings; provided that THERAVANCE shall reimburse MYLAN for [***] of MYLAN's out-of-pocket expenses with respect to the MYLAN Product Patents.

(c) Preparation, Prosecution and Maintenance of Joint Invention Patents.

i. Responsibility. THERAVANCE shall have the first right, and the obligation to prepare, file and prosecute in a diligent manner (including by conducting interferences, oppositions and reexaminations or other similar proceedings), and maintain (by timely paying all maintenance fees, renewal fees, and other such fees and expenses required under applicable Laws) and (subject to Section 2.02(f)) extend all Joint Invention Patents, in accordance with input from MYLAN as provided herein. THERAVANCE may elect not to prepare, file, prosecute, or maintain Joint Invention Patents, subject to the provisions of Section 12.02(d) and Section 12.02(h). The Parties agree to cooperate in the preparation and prosecution of all Joint Invention Patents, including by obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in Joint Invention Patents, and obtaining execution of such other documents which shall be needed in the filing and prosecution of Joint Invention Patents. Any Joint Invention Patents shall be filed in the name of both Parties and shall be owned jointly by THERAVANCE and MYLAN.

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ii. Abandonment. THERAVANCE must consult with MYLAN, and comply with Section 12.02(d), prior to the abandonment of any Joint Invention Patents.

iii. Input. THERAVANCE shall regularly advise MYLAN of the status of all Joint Invention Patents and shall provide MYLAN with copies of all material documentation concerning Joint Invention Patents, including all correspondence to and from any Governmental Authority. Prior to filing patent applications claiming Joint Inventions or significant prosecution documents relating to Joint Invention Patents, THERAVANCE shall solicit MYLAN's advice on the content of the patent application or prosecution document and THERAVANCE shall take into account and incorporate MYLAN's reasonable comments related thereto, unless (without fault of THERAVANCE) deadlines will not permit such review or MYLAN notifies THERAVANCE that it does not wish to review such documents.

iv. Expenses. Subject to a budget to be mutually agreed upon by the Parties and updated periodically, MYLAN will pay [***] of THERAVANCE's actual out-of-pockets expenses incurred after the Effective Date to procure Joint Invention Patents, including all filing fees, translations, maintenance, annuities, and protest proceedings. THERAVANCE shall be responsible for all of THERAVANCE's other expenses relating to Joint Invention Patents.

(d) MYLAN Step-In Rights. If THERAVANCE elects not to prepare and file a patent application claiming a patentable THERAVANCE Invention or Joint Invention or not to prosecute and maintain a THERAVANCE Patent or Joint Invention Patent in any Country in the Territory, THERAVANCE shall give MYLAN written notice thereof at least sixty (60) days prior to allowing any rights to such THERAVANCE Invention, Joint Invention, THERAVANCE Patent, or Joint Invention Patent, as applicable, to lapse or become abandoned or unenforceable, and MYLAN shall thereafter have the right ("Step-In Rights"), at its sole discretion and expense, to prepare and file a patent application or prosecute and maintain, as applicable, the relevant Patent in the relevant Country(ies). MYLAN shall provide THERAVANCE with written notice of its decision to exercise its Step-In Rights within thirty (30) days of receipt of the notice from THERAVANCE regarding its decision not to prepare or file a patent application on a THERAVANCE Invention or a Joint Invention or not to prosecute or maintain a THERAVANCE Patent or Joint Invention Patent. Within thirty (30) days of the exercise of Step-In Rights by MYLAN for any THERAVANCE Invention or a Joint Invention or THERAVANCE Patent or Joint Invention Patent in any Country, THERAVANCE shall assign all of its rights in and to the applicable Invention and/or the applicable Patent to MYLAN in that Country. Any such assigned THERAVANCE Invention, Joint Invention, Joint Invention Patent or THERAVANCE Patent shall thereafter be a MYLAN Invention or a MYLAN Patent in the assigned Country and be licensed in accordance with the terms of this Agreement for no additional consideration.

(e) Execution of Documents. Each of the Parties shall execute or have executed by its appropriate agents such documents as may be reasonably requested by the other Party to prepare, file, prosecute, maintain or extend any Patents in accordance with this Article 12, and each Party shall cooperate as reasonably requested by the other Party

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with respect to furnishing all information and data in its possession reasonably necessary to prepare, file, prosecute, maintain or extend any Patents in accordance with this Article 12, in each case at the requesting Party's expense.

(f) THERAVANCE Step-In Rights for MYLAN Product Patents. If MYLAN elects not to prosecute and maintain a MYLAN Product Patent in any Country in the Territory, MYLAN shall give THERAVANCE written notice thereof at least sixty (60) calendar days prior to allowing any rights to the MYLAN Product Patent to lapse or become abandoned or unenforceable, and THERAVANCE shall thereafter have the right, at its sole expense, to prosecute and maintain the MYLAN Product Patent in the relevant Country(ies). THERAVANCE shall provide MYLAN with written notice of its decision to exercise its Step-In Rights from and including thirty (30) calendar days of receipt of the notice from MYLAN regarding its decision not to prosecute or maintain a MYLAN Product Patent. From and including thirty (30) calendar days of the exercise of Step-In Rights by THERAVANCE for any MYLAN Product Patent in any Country, MYLAN will assign all of its rights in and to the MYLAN Product Patent to THERAVANCE in that Country. Any such assigned MYLAN Product Patent shall thereafter be a THERAVANCE Patent in the assigned Country and be licensed in accordance with the terms of this Agreement for no additional consideration.

(g) Patent Term Extensions. The Parties shall cooperate with each other to obtain patent term extensions or other extensions of patent rights, including if applicable supplementary protection certificates ("SPCs"), for the Licensed Products. The JSC shall determine which Patents the Parties shall endeavor to have extended in the Territory with respect to the Licensed Products in the Field. If the JSC does not agree as to which Patents should be extended in the Territory, then the Parties shall resort to the dispute resolution procedure set forth in Section 3.01(f); provided that in the event that MYLAN requests that THERAVANCE extend a THERAVANCE Patent claiming the composition of TD-4208 with respect to a Licensed Product in the Field, THERAVANCE will cooperate with MYLAN to do so. THERAVANCE shall be responsible for filing all such extensions for THERAVANCE Patents and Joint Invention Patents; and MYLAN shall be responsible for filing all such extensions for MYLAN Patents.

(h) Patent-Related Dispute Resolution. If the Parties disagree on any preparation, prosecution or maintenance issue for Patents within the scope of this Article 12 which is not specifically addressed and resolved by this ARTICLE 12 (a "Patent Resolution Issue"), the Parties agree to seek guidance and resolution from an independent, mutually acceptable patent attorney as further described in this Section 12.02(h) instead of resorting to the dispute resolution process as described in Section 3.01(f) (if applicable). If the Parties reach an impasse (remaining even after resort to the initial dispute resolution provided for in Section 3.01(f)(i)) as to any Patent Resolution Issue, then they shall submit the Patent Resolution Issue to an experienced patent attorney mutually-acceptable to the Parties, who does not otherwise perform work for either Party or any of its Affiliates, for resolution. The Parties shall engage such attorney within thirty (30) days of either Party notifies the other in writing of a Patent Resolution Issue impasse remaining unresolved after resort to Section 3.01(f)(i). If they cannot agree as to who such attorney shall be within such time period, then the total of two nominees of the

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Parties (one from each Party) shall select a third patent attorney who shall be the attorney to resolve the dispute. The Parties shall share equally the expenses incurred for the services of such patent attorney. Within fifteen (15) days of engaging the patent attorney, the Parties shall each submit up to twenty (20) pages of documentation to the patent attorney. Within five (5) Business Days of such submission, the Parties shall convene a meeting with the patent attorney during which each Party may orally present its position on the Patent Resolution Issue for no more than one (1) hour. The Parties shall endeavor to cause the patent attorney to render his or her guidance as to the Patent Resolution Issue within five (5) Business Days of such discussion. Neither Party shall engage in any ex parte communications with the patent attorney. The Parties shall accept and follow the guidance and resolution of the patent attorney absent any fraud in the proceedings.

Section 12.03 Patent Infringement.

(a) Infringement Claims by Third Parties. With respect to any and all Claims instituted by Third Parties against THERAVANCE or MYLAN or any of their respective Affiliates for patent infringement based on the manufacture, use, license, marketing, sale, offer for sale or importation of TD-4208 or Licensed Product in the Territory during the Term (a "Patent Infringement Claim"), THERAVANCE and MYLAN will assist one another and cooperate in the defense and settlement of such a Patent Infringement Claim at the other Party's request and expense, including by joining as a party-plaintiff where necessary under applicable Laws. The Party that is subject to the Patent Infringement Claim shall have the exclusive right to defend and control the defense of such Patent Infringement Claim at its own expense, and shall keep the other Party reasonably informed of all material developments in such defense. The defending Party shall not enter into a settlement of a Patent Infringement Claim that would adversely affect or diminish the rights or benefits of the other Party under this Agreement to any material extent without such other Party's consent, not to be withheld, refused, conditioned or delayed unreasonably.

(b) Patent Infringement Notice. In the event that either Party becomes aware of actual or threatened infringement of a THERAVANCE Patent, MYLAN Patent, or Joint Invention Patent during the Term, that Party will promptly notify the other Party in writing (a "Patent Infringement Notice").

(c) Infringement of THERAVANCE Patents. THERAVANCE will have the first right but not the obligation to enforce the THERAVANCE Patents against any Third Party. If THERAVANCE elects to pursue such an enforcement action, THERAVANCE shall be solely responsible for the expenses associated with such action. During the Term, in the event that THERAVANCE does not undertake such an enforcement action within ninety (90) days of the Patent Infringement Notice, MYLAN shall be permitted to do so in THERAVANCE's name and, if it elects to undertake such an enforcement action, MYLAN shall be solely responsible for the expenses associated with such action. If a Party is authorized to bring an infringement action under this Section 12.03(c) but the Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall, at the enforcing Party's request and expense, join as a party-plaintiff. If THERAVANCE recommends

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not to enforce the THERAVANCE Patents in response to a Patent Infringement Notice, and MYLAN elects to pursue such enforcement action by joining THERAVANCE as a party plaintiff, then MYLAN agrees to indemnify and hold harmless THERAVANCE for all Losses incurred by THERAVANCE in such enforcement action.

(d) Infringement of MYLAN Patents. In the event that either Party becomes aware of actual or threatened infringement of a MYLAN Patent during the Term, that Party will promptly send a Patent Infringement Notice to the other Party. MYLAN will have the first right but not the obligation to enforce the MYLAN Patents against any Third Party. If MYLAN elects to pursue such an infringement action, MYLAN shall be solely responsible for the expenses associated with such action. During the Term, in the event that MYLAN does not undertake such an infringement action with respect to a MYLAN Product Patent within ninety (90) calendar days of the Patent Infringement Notice, THERAVANCE shall be permitted to do so in MYLAN's name and THERAVANCE shall be solely responsible for the expenses associated with such action. If a Party is authorized to bring an infringement action under this section but such Party is not recognized by the applicable court or other relevant body as having the requisite standing to pursue such action, then the other Party shall join as a party-plaintiff at the enforcing Party's expense. If MYLAN recommends not to pursue an infringement action, and THERAVANCE elects to pursue such infringement action by joining MYLAN as a party plaintiff, then THERAVANCE agrees to indemnify and hold harmless MYLAN for all losses and damages arising from the infringement action.

(e) Infringement of Joint Invention Patents. In the event that either Party becomes aware of actual or threatened infringement of a Joint Invention Patent during the Term, that Party will promptly send a Patent Infringement Notice to the other Party. In such an event, the matter will be handled as provided in Section 12.03(c).

Section 12.04 Notice of Certification. Each Party shall promptly give notice to the other of its receipt of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" as amended or as it may be amended (or its foreign equivalent) claiming that any Patent listed in the Orange Book for a Licensed Product in the Field is invalid or that infringement will not arise from the manufacture, use or sale of the Licensed Product by a Third Party ("Hatch-Waxman Certification"). This Section 12.04 is intended by the Parties to apply to any successor legislation in the U.S. to the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" and to any counterpart or similar legislation outside the U.S.

(a) Enforcement of Patent. Notwithstanding anything in this Article 12 to the contrary, THERAVANCE shall have the first right to enforce the THERAVANCE Patents against a Third Party filing a Hatch-Waxman Certification and MYLAN shall have the first right to enforce the MYLAN Patents and the Joint Invention Patents against a Third Party filing a Hatch-Waxman Certification. If THERAVANCE decides to bring an enforcement action against the entity making a Hatch-Waxman Certification, THERAVANCE shall permit MYLAN to join as a party to such action (to the extent permitted by Law) and solicit MYLAN's input and advice, and the Parties shall cooperate with respect to such enforcement action. If MYLAN decides to bring an enforcement

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action against the entity making a Hatch-Waxman Certification, MYLAN shall solicit THERAVANCE's input and advice, and the Parties shall cooperate with respect to such enforcement action. The Party with the first right under this Section 12.04(a) to bring an enforcement action against the entity making a Hatch-Waxman Certification shall give notice to the other Party of its decision whether or not to bring such an action within twenty-one (21) days of receipt of notice of such Hatch-Waxman Certification.

(b) Option. Upon receipt of a notice from the non-enforcing Party of its decision not to enforce the applicable Patents in response to a Hatch-Waxman Certification, the other Party then may, but is not required to, enforce the THERAVANCE Patents, the MYLAN Patents or the Joint Invention Patents, as applicable, against the Third Party that filed the Hatch-Waxman Certification.

(c) Name of Party. Any enforcement action brought by either Party pursuant to this Section 12.04 shall be brought in the name of THERAVANCE or in the name of MYLAN or jointly in the names of THERAVANCE and MYLAN, as may be required by Law, and each Party shall join as a party-plaintiff as reasonably requested by the enforcing Party to satisfy such requirement.

(d) Representation of Other Party. If a Party elects to pursue an enforcement action under this Section 12.04, the other Party not bringing suit may be represented in such an action by attorneys of its own choice and at its own expense. The Party bringing suit shall take the lead in and control any such action.

Section 12.05 Settlement. No settlement or consent judgment or other voluntary final disposition of any enforcement action under this Article 12 that would adversely affect or diminish the rights or benefits of a Party under this Agreement to any material extent may be entered into without the joint written consent of such Party (which consent will not be withheld, refused, conditioned or delayed unreasonably).

Section 12.06 Assistance. Each Party shall execute any legal papers necessary for the enforcement of the THERAVANCE Patents and Joint Invention Patents under this ARTICLE 12 and shall provide reasonable assistance, in each case as requested by the enforcing Party. Such assistance shall be at the expense of the Party bringing suit on a pass-through basis.

Section 12.07 Disposition of Recoveries. Any damages, awards, settlement payments or other recoveries resulting from an enforcement action brought by the Parties pursuant to this Article 12 with respect to a THERAVANCE Patent or Joint Invention Patent with respect to infringements in the Field during the Term shall be allocated as follows: (i) the Party bringing the infringement action shall be reimbursed for all expenses incurred in connection with bringing and maintaining the infringement action; (ii) the remainder of the recovery, after payment of expenses, shall be split [***] to MYLAN and [***] to THERAVANCE. Subject to the Parties' indemnification obligations under Article 11 and except as otherwise set forth in this Article 12, any damages or other losses incurred by the Parties or their Affiliates as a result of an enforcement action brought by the Parties pursuant to this Article 12 ("Enforcement Damages") shall be Shared Expenses.

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ARTICLE 13
TERM AND TERMINATION

Section 13.01 Term and Expiration of Term. Except as otherwise mutually agreed to by the Parties, this Agreement shall commence on the Effective Date and shall end upon expiration of the Term, unless terminated earlier as contemplated in this Article 13.

Section 13.02 Termination for Material Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement subject to ARTICLE 14 in the event that the other Party (as used in this subsection, the "Breaching Party") shall have materially breached this Agreement or defaulted in the performance of any of its obligations hereunder, and not corrected the situation following notice and an opportunity to cure as provided below. The Breaching Party shall have sixty (60) days of written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default (or, if such default cannot be cured within such 60-day period, the Breaching Party must commence actions to cure such default during such 60-day period and thereafter diligently continue such actions). Any such termination shall become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period (or, if such default is capable of being cured but cannot be cured within such 60-day period, the Breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within ninety (90) days of written notice thereof being provided to the Breaching Party by the non-breaching Party to remedy such default). In the event that one Party claims that the other Party has materially breached its obligations hereunder, and the Breaching Party (by written notice to the other Party) disputes in good faith such material breach or its failure to cure such breach within the applicable cure period, then such dispute may be submitted to dispute resolution, either pursuant to the procedures set forth in Section 3.01(f) or through litigation or arbitration. In such event, the Party alleging such breach does not have the right to terminate this Agreement pursuant to this Section 13.02, until it has been determined, pursuant to such dispute resolution procedure, that the Breaching Party is in material breach of this Agreement, and such Breaching Party further fails to cure such breach within sixty (60) days after the conclusion of any such procedure. For clarity, in the event of a material breach by MYLAN with respect to a particular ROW Country, THERAVANCE's right to terminate under this Section 13.02 would apply on a Country-by-Country basis as set forth in Section 5.04(f).

Section 13.03 Termination by MYLAN. MYLAN shall have right to the terminate this Agreement, upon one hundred eighty (180) days prior written notice to THERAVANCE, (a) at any time with respect to one or more ROW Countries, or (b) in its entirety in the event that (i) final approval of the first NDA for a Licensed Product in the Field in the U.S. in not received prior to December 31, 2021, (ii) the Development Expenses required to obtain such approval exceed, or are reasonably expected to exceed, those set forth in the Preliminary Development Plan by more than [***], or (iii) in the event that MYLAN is required to divest the Licensed Product in the Field by a Governmental Authority (in

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which case such termination will only be on a Country-by-Country basis); provided that if such termination is of this Agreement in its entirety, THERAVANCE shall be permitted to wind-down the Development of the Licensed Product in the Field pursuant to the Development Plan or continue such Development, either itself or with a Third Party, and MYLAN shall reimburse THERAVANCE's Development Expenses during the period between MYLAN's notice of termination and the effective date of such termination, not to exceed [***]. If THERAVANCE elects to wind-down the Development of the Licensed Product in the Field pursuant to this Section 13.03, THERAVANCE shall promptly cease enrolling any further patients in any ongoing clinical trial, cease dosing subjects in such trials with Licensed Product as soon as reasonably practicable without jeopardizing patient safety, cease incurring additional expenses that have not already been committed to, and mitigate those expenses to which THERAVANCE is already committed to the extent practicable.

Section 13.04 Contemporaneous Termination of China RFN and RFN. The China RFN and RFN shall terminate automatically at the time of any early termination of this Agreement in its entirety under this ARTICLE 13, except for a termination by MYLAN under Section 13.02 for THERAVANCE's material breach.

Section 13.05 Accrued Rights; Surviving Provisions. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement, including without limitation Articles 1, 9, 11, 14, and 15 Sections 4.03(f), 6.08, 7.03, 10.05 and 13.05. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available to the Parties in law or equity.

ARTICLE 14
CONSEQUENCES OF TERMINATION

Section 14.01 Termination by Natural Expiry of Term.

(a) Upon expiration of this Agreement under Section 13.01:

i. any exclusive license granted under Section 2.01 shall survive and become non-exclusive and all licenses granted by THERAVANCE to MYLAN pursuant to Section 2.01 shall survive and become fully-paid up, perpetual and irrevocable.

ii. any exclusive license granted under Section 2.02(c) or (d) shall survive and become non-exclusive, fully-paid up, perpetual and irrevocable.

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Section 14.02 Termination by THERAVANCE Under Section 13.02. Upon the effective date of termination of this Agreement in its entirety (the "Date of Termination") by THERAVANCE pursuant to Section 13.02:

(a) the licenses and rights granted under Section 2.01 and 2.02 shall cease;

(b) the Parties will negotiate in good faith the terms and conditions on which MYLAN shall:

i. grant to THERAVANCE the following non-exclusive, royalty-free licenses, which shall replace those license grants made pursuant to Section 2.02, subject to the surviving terms of this Agreement:

(A) a license under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to Develop Licensed Products in the Field worldwide;

(B) a license under the MYLAN Patents and MYLAN Know-How and Joint Invention Patents to Commercialize Licensed Products in the Field worldwide; and

(C) a license under: (i) the MYLAN Patents and MYLAN Know-How and Joint Invention Patents solely to make and have made anywhere in the world formulated Licensed Product in the Field and (ii) the MYLAN Patents to the extent claiming Improvements and MYLAN Know-How comprising Improvements solely to make and have made anywhere in the world API Compound for incorporation into Licensed Products for purposes of Developing and Commercializing Licensed Product in or outside the Field worldwide.

ii. subject to Article 9, destroy all THERAVANCE Know-How and, at THERAVANCE's request and expense, deliver to THERAVANCE a copy of all MYLAN Know-How in written form;

iii. promptly after THERAVANCE's request and at THERAVANCE's expense, deliver to THERAVANCE at the location specified by THERAVANCE any and all quantities of API Compound and Licensed Product in its possession, power, custody or control, subject always to MYLAN's right to dispose of Licensed Product which is the subject of pre-termination date orders in accordance with clause (vi) below. THERAVANCE shall pay for the quantities thus transferred to it in an amount equal to [***] for such quantities;

iv. commensurate with legislative and regulatory requirements, transfer to THERAVANCE or its nominee all Marketing Authorizations and Regulatory Filings for the Licensed Product in the Field in the Territory, at THERAVANCE's request and expense;

v. assign, or grant a worldwide, royalty-free exclusive license, to THERAVANCE to use the Trademarks used on the Licensed Product in the Field at the time of such termination for use on such Licensed Product in the Field;

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vi. for a period of six (6) months after the Date of Termination, MYLAN has the right to dispose of that part of its inventory of Licensed Product on hand as of the Date of Termination which is the subject of orders for Licensed Product accepted prior to MYLAN's receipt of notice of termination, and, within sixty (60) days of disposition of such inventory pursuant to the fulfillment of such orders, MYLAN will forward to THERAVANCE a final report and pay THERAVANCE its share of Operating Profits (Losses) and/or Royalties due with respect to such Licensed Products in accordance with this Agreement;

vii. at the request of THERAVANCE, for a period of up to twenty-four (24) months following the Date of Termination, manufacture or supply such API Compound and Licensed Product in the Field, if any, that are being manufactured by or for MYLAN prior to such termination ("Supplied Licensed Product") to THERAVANCE or to THERAVANCE's designee. Such Supplied Licensed Product shall be provided to THERAVANCE at [***] in respect of such supply. During said twenty-four (24) month period, MYLAN shall manufacture API Compound and Licensed Product in the Field up to the quantities set forth in the current updated forecast for Licensed Product as of the Date of Termination as set forth in the Commercialization Plan and THERAVANCE shall accept such quantities of API Compound or Licensed Product. MYLAN shall also provide THERAVANCE, at THERAVANCE's request and expense, with reasonable assistance in relation to THERAVANCE's transition a Third Party manufacturer of Licensed Product in the Field.

(c) Disclosure of Confidential Information. Upon the Date of Termination by THERAVANCE under Section 13.02 or by MYLAN pursuant to Section 13.03, THERAVANCE shall have the right to disclose Confidential Information of MYLAN that is generated pursuant to this Agreement, under customary and reasonable legally binding obligations of confidentiality and non-use, to Third Parties for the purpose of, and solely to the extent necessary for, enabling such Third Parties to evaluate the financial and scientific status of the Licensed Products for the purpose of making an offer to THERAVANCE on the licensing or acquisition of the rights returned to THERAVANCE and the rights licensed to THERAVANCE under this ARTICLE 14, and, if such licensing or acquisition occurs, solely to the extent necessary to exploit or enforce such rights. For clarity, this Section 14.02(c) shall not be deemed to grant THERAVANCE any right or license under any Patent, copyright or trademark of MYLAN.

Section 14.03 Termination by MYLAN Under Section 13.02.

(a) Upon the Date of Termination of this Agreement by MYLAN pursuant to Section 13.02:

i. The licenses and rights granted under Section 2.02 shall cease;

ii. THERAVANCE's share of Operating Profits in the U.S. under Section 1.03 of Exhibit F shall be reduced by [***];

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iii. THERAVANCE's licenses and rights granted to MYLAN under Section 2.01 shall continue, subject to MYLAN's continued obligation to pay Royalties to THERAVANCE under Section 1.04 of Exhibit F at rates equal to [***] of the rates set forth therein, for a period that would be the remainder of the Term, had it not been terminated.

iv. The JSC and JPC shall be disbanded, the Co-Promotion Agreement shall terminate, and THERAVANCE shall no longer have the right to receive any Development or Commercialization reports or other information from MYLAN other than as required to determine the amount of continuing shared Operating Profits and Royalties owed hereunder;

v. Sections 2.07 and 2.08 shall survive; and

vi. MYLAN shall be entitled to conduct all enforcement against infringement within the scope of the licenses to MYLAN hereunder (treating all recoveries over expenses as Net Sales in the Territory), and THERAVANCE will join as a party plaintiff in any such enforcement action with respect to the THERAVANCE Patents and Joint Invention Patents, at MYLAN's reasonable request and expense.

(b) Disclosure of Confidential Information. Upon the Date of Termination by MYLAN under Section 13.02, THERAVANCE shall, subject to Article 9, destroy all MYLAN Know-How and deliver to MYLAN a copy of all THERAVANCE Know-How in written form, which MYLAN shall be permitted to use and disclose in accordance with Article 9, including with respect to all rights surviving such termination.

ARTICLE 15
MISCELLANEOUS

Section 15.01 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval, except as expressly set forth in this Agreement. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, MYLAN's legal relationship under this Agreement to THERAVANCE shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

Section 15.02 Registration and Filing of This Agreement. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority, including the

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U.S. Securities and Exchange Commission or the U.S. Federal Trade Commission, in accordance with applicable Laws, such Party shall inform the other Party thereof. Should both Parties jointly agree that either of them is required to submit or obtain any such filing, registration or notification, they shall cooperate, each at its own expense, in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Law, and will involve each other in a reasonable fashion to help ensure each Party's confidentiality concerns are addressed to the extent permissible. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information there from on a timely basis.

Section 15.03 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its Affiliates, not due to malfeasance by such Party or its Affiliates, and which could not with the exercise of reasonable effort have been avoided (each, a "Force Majeure Event"), including an injunction, inability to obtain raw materials, delay or errors by shipping company, fire, accident, riot, civil commotion, act of God, or change in Laws, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such obligation to perform during the continuation of the Force Majeure. The Party prevented from performing its obligations or duties because of a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected shall use Diligent Efforts to avoid or remove such causes of nonperformance and resume performance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, provided such Party complies in all material respects with its obligations under this Section 15.03.

Section 15.04 Governing Law. This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of New York notwithstanding the provisions governing conflict of laws under such New York law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property Laws relevant to the intellectual property in question.

Section 15.05 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed (except with respect to an assignment by THERAVANCE to a Change of Control Conflict Company, in which case MYLAN may grant or withhold its consent in

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its sole discretion). Notwithstanding the foregoing, either Party may assign this Agreement (a), in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate to which this Agreement is assigned in part, or (b) to a successor to all or substantially all of the assets of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction or by operation of law; provided that THERAVANCE may only assign this Agreement to a Change of Control Conflict Company pursuant to this clause (b), without the prior written consent of MYLAN, if such Change of Control Conflict Company is (i) a successor to all or substantially all of the assets of THERAVANCE or (ii) a successor to all or substantially all of the assets of THERAVANCE related to TD-4208. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns. Notwithstanding the foregoing, in the event that THERAVANCE is subject to a Change of Control in which a Change of Control Conflict Company is the acquiring party or this Agreement is otherwise assigned to a Change of Control Conflict Company in accordance with this Section 15.05, THERAVANCE shall, within two (2) days after the date that such merger or acquisition closes or the date of such assignment, as applicable, (the "Closing Date"), provide MYLAN with notice of such Change of Control or assignment, and, effective as of the Closing Date, (a) any and all diligence obligations on MYLAN hereunder shall be of no further force and effect, and MYLAN shall not be obligated to submit any further updates to the Commercialization Plan to THERAVANCE or the Change of Control Conflict Company, (b) except as provided in (e) below, neither THERAVANCE nor the Change of Control Conflict Company shall have any further right of input or insight into MYLAN's Commercialization of the Licensed Products in the Field hereunder, (c) MYLAN shall have the right to terminate the Co-Promotion Agreement and THERAVANCE's right (and any right the Change of Control Conflict Company may have) to Commercialize the Licensed Products in the Field in the U.S., (d) MYLAN shall not be obligated to reimburse THERAVANCE or the Change of Control Conflict Company for any Development Expenses incurred after the Closing Date, unless MYLAN requests in writing, after the Closing Date, that THERAVANCE complete the Development activities pursuant to which THERAVANCE incurs such Development Expenses, in which case THERAVANCE shall complete such Development activities; (e) MYLAN shall have no further reporting or record-keeping obligations hereunder with respect to the Development or Commercialization of, and regulatory activities for, the Licensed Products in the Field other than its financial reporting and record-keeping obligations under Exhibit F, and (f) MYLAN shall have no further obligation to disclose to THERAVANCE or the Change of Control Conflict Company the MYLAN Product Trademarks or the MYLAN Know-How hereunder and any MYLAN Know-How developed or reduced to practice after the Closing Date or MYLAN Patents filed after the Closing Date shall not be included within the scope of the licenses granted to THERAVANCE under Section 2.01. For purposes of the foregoing, a "Change of Control" shall mean the acquisition of voting shares of THERAVANCE by a Person that results in such Person holding more than fifty percent (50%) of the voting shares of THERAVANCE. In the event that THERAVANCE is subject to a Change of Control in which the acquiring party is not a Change of Control Conflict Company or otherwise assigns this Agreement in accordance with this Section

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15.05 to a Person that is not a Change of Control Conflict Company, this Agreement shall continue in accordance with its terms; provided that, effective upon the Closing Date, MYLAN shall have final decision-making authority with respect to all JSC matters after they are escalated to the Officers pursuant to Section 3.01(f)(i) and such matters shall not go to arbitration in accordance with Section 3.01(f)(ii).

Section 15.06 Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if delivered personally, by facsimile with confirmation of receipt, by mail (first class, postage prepaid), or by overnight delivery using a globally recognized carrier, to the Parties at the following addresses:

THERAVANCE:	Theravance Biopharma R&D, Inc. c/o Theravance Biopharma US, Inc. 901 Gateway Boulevard South San Francisco, CA 94080 Facsimile: [***] Attn: Head of Business Development
With a copy to:	Legal Department Theravance Biopharma R&D, Inc. c/o Theravance Biopharma US, Inc. 901 Gateway Boulevard South San Francisco, CA 94080 Facsimile: [***]
MYLAN:	Mylan Ireland Limited 6th Floor, South Bank House Barrow Street Dublin 4 Ireland Attn: Peter McCormick, Director
With a copy to:	Mylan Inc. 1000 Mylan Boulevard Canonsburg, PA 15317 Facsimile: (724) 514-1871 Attn: Global General Counsel

or to such other address as the addressee shall have last furnished in writing in accord with this provision to the addressor. All notices shall be deemed effective upon receipt by the addressee.

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Section 15.07 Severability. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions which most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable Laws.

Section 15.08 Amendment; Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

Section 15.09 Entire Agreement. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties with respect to such subject matter, whether written or oral. No Party has entered into this Agreement in reliance upon any statement, representation, warranty or undertaking made by or on behalf of any other Party other than those expressly set out in this Agreement. This Agreement may be altered, amended or changed only in writing and by making specific reference to this Agreement and signed by duly authorized representatives of THERAVANCE and MYLAN.

Section 15.10 No License. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right to either Party, in respect of any product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

Section 15.11 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

Section 15.12 Counterparts. This Agreement may be executed in any two counterparts, each of which, when executed, shall be deemed to be an original and both of which together shall constitute one and the same document.

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IN WITNESS WHEREOF, THERAVANCE and MYLAN, by their duly authorized officers, have executed this Agreement.

THERAVANCE BIOPHARMA R&D, INC.	MYLAN IRELAND LIMITED
By: /s/ Brett K Haumann	By: /s/ Peter McCormick
Brett K. Haumann Senior Vice President, Clinical Development	Peter McCormick Director

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EXHIBIT A

Chemical Structure of TD-4208

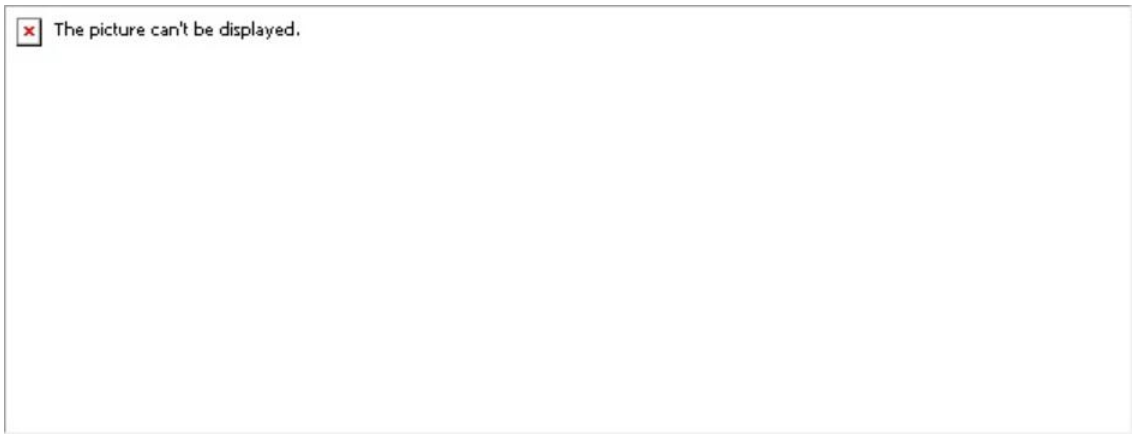

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EXHIBIT B

Patents

Version Date: On Execution

I. THERAVANCE Patents

[***]

II. MYLAN Patents

[***]

III. Joint Invention Patents

[***]

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EXHIBIT C
Initial JSC Members

MYLAN:
[***]
THERAVANCE:
[***]

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EXHIBIT D
CO-PROMOTION AGREEMENT TERMS AND CONDITIONS

The Co-Promotion Agreement shall incorporate the terms and conditions described in this Exhibit D below as well as other terms and conditions standard and customary for these types of agreements and consistent with the terms and conditions of the Agreement and the following:

Definitions: "Co-Promote" means joint conduct of Direct Promotional Activities through MYLAN's and THERAVANCE's respective commercial personnel under the Trademark and MYLAN taking the predominant role and managing General Promotional Activities, distribution and booking sales for the Products in the U.S. "**Co**-Promoting" and "Co-Promotion" have their correlative meanings.

"Direct Promotional Activities" means, as to be defined in more detail in the Co-Promotion Agreement, (a) those sales and promotional activities generally performed by Sales Representatives in the U.S., including detailing and other similar communications, (b) non-personal promotional activities (e.g., e-detailing, tele-detailing and channel marketing), and (c) medical / health economic marketing and support activities generally performed by Medical Representatives, in each case, (a) - (c), directly to (i) appropriate health care professionals with prescribing or similar authority for the applicable Product or (ii) Persons responsible for overseeing or managing (A) pharmacy or prescription drug benefits, utilization and/or capitation, (B) formulary/preferred drug program inclusion and maintenance, or (C) health outcomes support services and physician/patient advocacy, or, in each case, (A) - (C), similar functions (Persons described in (i) and (ii) collectively, "Responsible Persons").

"General Marketing Activities" means, as to be defined in more detail in the Co-Promotion Agreement, any and all Commercialization activities including marketing and promotional activities and healthcare and consumer educational programs that are standard and customary for products similar to Licensed Products in the U.S., including the following:

· Generating Promotional Materials;

· Conducting market research and acquiring applicable market data;

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· Branding

· Working with marketing vendors (e.g., public relations agencies, advertising agencies and medical education agencies) to develop applicable marketing campaigns; and

· Coordinating and implementing (a) publications, journal and magazine advertisements (both paper and electronic) (b) media production; and (c) patient marketing activities (patient education, direct patient marketing, direct to consumer advertising, direct mail, web site development and maintenance and the like).

"Medical Representative" means an individual medical scientific liaison, health economics and outcomes researcher and any individual having similar medical support functions.

"Sales Representative" means an individual sales representative (including a field sales representative, institutional sales representative, pharmacy/trade sales representative or managed care sales representative) and any individual having similar direct sales or marketing functions.

General: Each Party will participate in the Co-Promotion of Licensed Product in the U.S. as set forth in the Commercialization Plan and as described generally below.

Direct Promotional Activities. Unless THERAVANCE provides MYLAN at least twelve (12) months prior notice, that it will not participate in Direct Promotional Activities(1), then each Party will through its Sales Representatives and Medical Representatives (collectively, the "Sales Force"), the number of each will be specified in the Commercialization Plan by Party, be responsible for conducting those Direct Promotional Activities in the U.S. assigned to it in the Commercialization Plan. The Parties shall conduct such activities in accordance with the Commercialization Plan and will coordinate with each other with respect thereto.

Responsibility for Licensed Product details to specific target Responsible Persons will be apportioned to each Party by market segment (including customer segments, including channel, payer, managed care and government affairs), such apportionment will also include prioritization and targets for the number of times

(1) In the event that THERAVANCE notifies MYLAN that it will not participate, then from the effective date of such notice, MYLAN shall be solely responsible and have the right to conduct all Direct Promotional Activities and other activities under the Commercialization Plan.

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specific groups of Responsible Persons will be detailed each year and allocable Sampling programs. The Parties will coordinate its performance of Direct Promotional Activities with the goal of ensuring coordination and transparency between the Parties, including, sharing marketing intelligence, call lists and the results of such efforts in a reasonably expeditious and detailed manner in order to preserve the relevance and utility thereof.

MYLAN will be responsible for providing professional services and Medical Representatives with respect to and in support of the Direct Promotional Activities for Licensed Product; however, THERAVANCE may provide a mutually agreed number of Medical Representatives.

General Marketing Activities: MYLAN will be responsible for the performance of the General Marketing Activities in the U.S. as set forth in the Commercialization Plan.

Each Party will be responsible for maintaining Samples and records thereof in accordance with application Laws.

Reimbursement: MYLAN will be responsible for establishing and implementing appropriate reimbursement / payer strategies with respect to Licensed Product in the U.S. as set forth in the Commercialization Plan, which may include:

· Obtaining (i) reimbursement coding for Medicare, (ii) coverage and payment by the Veteran's Administration and at Vertical Integrated Service Networks (VISNs), (iii) inclusion on the Federal Supply Schedule, (iv) inclusion on applicable formularies and reimbursement by identified managed care and national private payer accounts; and

· Establishing hotline service mechanism for patient/physician assistance program and a reimbursement hotline for Licensed Product.

Hiring: Each Party will be responsible for recruiting and hiring its own Sales Force for the conduct of activities under the Commercialization Plan. Each Party will be responsible for incentive compensation programs aimed at appropriately incentivizing its Sales Force to effectively promote Licensed Products and otherwise conduct their activities under the Commercialization Plan, provided that the Parties may agree to coordinate such compensation. Each Party will be responsible for

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the actions of its own Sales Force and other personnel and their compliance with applicable Law, MYLAN's Code of Conduct, and otherwise the highest levels of ethical and business conduct. The Sales Force of one Party shall not be considered an employee of the other Party, nor entitled to any compensation or benefits from such other Party.

Training: MYLAN (in consultation with the JPC) will develop and implement training program(s) for the Parties' Sales Forces. Promptly after such training programs have been developed each Party will ensure that each of its Sales Representatives, Medical Representatives and other related support personnel for Licensed Product complete the applicable training program (as updated from time to time) and pass certain qualification criteria. Accordingly, each Party will allocate time at each of its Sales Force meetings for updated training with respect Licensed Product.

Promotional Material: MYLAN will develop and provide to the Parties' Sales Forces all Promotional Material and other sales materials and aids for use in the promotion and sale of Licensed Product in the Field will be developed in accordance with the applicable guidelines established in the then-current version of the Commercialization Plan and Commercial Budget and subject to the oversight of the JPC.

Administrative Services: MYLAN will coordinate administrative services for the Parties' Sales Forces Co-Promotion Activities in the U.S including:

· Territory/market alignment;

· Data management, including: compiling and analyzing Licensed Product sales data, market data (including data relating to competitive sales), and data related to the tracking of the Direct Promotional Activities of the Parties; and

· Sales Force automation matters.

Meetings: MYLAN and THERAVANCE will jointly participate in and staff all major and regional scientific and trade meetings designated in the Commercialization Plan.

Costs: Each Party will bear its own costs in conducting activities under the Co-Promotion Agreement, except that certain of such costs will be shared in the context of the sharing of Operating Profits (Losses) under the Agreement.

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Reporting: MYLAN will report on its activities under the Commercialization Plan at each JPC and JSC meeting.

Term: The term of the Co-Promotion Agreement will be coextensive with the Agreement. The Co-Promotion Agreement will be subject to termination on the same terms as the Agreement.

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EXHIBIT E

Commercialization Plan Outline

[***]

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EXHIBIT F

Financial Exhibit

Section 1.01 Upfront Payment. MYLAN shall pay to THERAVANCE a non-refundable fee of Fifteen Million United States Dollars (U.S. $15,000,000) (the "Upfront Payment") in partial consideration for the rights and licenses granted to it under this Agreement. MYLAN shall become obligated to pay the Upfront Payment 120 days after the Effective Date.

Section 1.02 Milestone Payments.

(a) General. In further consideration for the acquisition of license rights under the THERAVANCE Patents, THERAVANCE Know-How and the Joint Invention Patents under Section 2.01, MYLAN shall also pay to THERAVANCE the one-time payments set forth below for the first occurrence of the corresponding Development Milestone or Sales Milestone referred to therein (each, a "Milestone"):

Development Milestones	**Amount**
[***]	

Sales Milestones	**Amount**
[***]	

(b) Payment Only Once for Milestones. For the avoidance of doubt, Milestones are each payable only once, upon first attainment of the relevant milestone, regardless of how many times a Milestone is reached. In the event that more than one Sales Milestones are achieved in a given Calendar Year then the lower Sales Milestone payment for the Stand Alone Licensed Product would be payable for that Calendar Year and the higher Sales Milestone would be payable at the end of the following Calendar Year provided that the higher Sales Milestone is achieved and/or maintained in the following Calendar Year.

(c) Notification and Payment. In the event of attainment of a Milestone, a Party shall promptly, but in no event more than ten (10) Business Days after the achievement of each such Milestone, notify the other Party in writing of the achievement of same. For each Milestone achieved, MYLAN shall promptly, but in no event more than ten (10) Business Days after receipt of THERAVANCE's invoice therefore, remit payment to THERAVANCE for such Milestone.

Section 1.03 Operating Profit (Loss) Share in the U.S.

(a) The Parties shall share the Operating Profits (Losses) from the sale of the Licensed Products in the Field in the U.S as set forth in this Section 1.03. The Parties

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expect that Net Sales in the U.S. shall be accounts receivable of MYLAN and MYLAN shall receive payment on account thereof.

(b) During the Term, MYLAN and THERAVANCE shall split the Operating Profits (Losses), sixty-five percent (65%) to MYLAN and thirty-five percent (35%) to THERAVANCE.

(c) In the event that both Parties elect to sublicense the Commercialization of the Licensed Products in the Field in the U.S. to a Third Party, all cash consideration received in consideration for the grant of such sublicense will be treated as Net Sales in the U.S. For clarity, any such sublicense must be agreed by both Parties. In the event that one Party sublicenses the Commercialization of the Licensed Products in the Field in the U.S. to a Third Party, the sharing of Operating Profits (Losses) shall, as between the Parties, remain as set forth in Section 1.03(b) of this Exhibit F.

(d) The sharing of Operating Profits (Losses) set forth in this Section 1.03 shall be reported, calculated and paid in accordance with Section 1.07 below.

Section 1.04 Payment of Royalties to THERAVANCE on Net Sales in the ROW Countries.

(a) As further consideration for the acquisition of license rights under the THERAVANCE Patents and THERAVANCE Know-How under this Agreement, MYLAN shall pay to THERAVANCE royalties on Net Sales of Licensed Products in the Field in the ROW Countries that either (i) are covered by a Valid Claim within a THERAVANCE Patent or (ii) incorporate the THERAVANCE Know-How, Less ROW Recall Costs ("Adjusted Net Sales"), in the following percentages ("Royalties"):

On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries up to U.S. [***]	[***]
On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries over U.S. [***] and less than U.S. [***]:	[***]
On the portion of annual Adjusted Net Sales of Licensed Product in the Field in the ROW Countries over U.S. [***]:	[***]

(b) Notwithstanding the foregoing, the Royalties shall be reduced by [***] with respect to Licensed Products that are not covered by a Valid Claim within the THERAVANCE Patents in the Country of sale. For purposes of the foregoing, "cover" means that the manufacture, use, sale or importation of a Licensed Product would infringe a Valid Claim within the THERAVANCE Patents but for the licenses granted to MYLAN herein.

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Section 1.05 Duration of Royalty Payments to THERAVANCE.

(a) Commencement. All royalties payable under Section 6.05(a) shall be paid on a Country-by-Country basis from First Commercial Sale of the Licensed Product in the relevant ROW Country.

(b) Duration of Royalties; Adjustment of Royalties. Royalty obligations under Section 6.05 shall apply on a Country-by-Country basis, until the later of (i) the expiration or termination of the last Valid Claim of a THERAVANCE Patent or Joint Invention Patent covering the Licensed Product in the ROW Country of sale and (ii) thirteen (13) years from First Commercial Sale of the Licensed Product anywhere in the Territory.

Section 1.06 Payments to Third Parties; Combination Products.

(a) Payments to Third Parties. If MYLAN is required to pay any amounts to a Third Party with respect to the manufacturing, using or selling Licensed Product in a ROW Country based on the intellectual property rights of such Third Party covering such Licensed Product, MYLAN shall be entitled to deduct [***] of any such amount paid to such Third Party from the Royalties otherwise due THERAVANCE for such Licensed Product, provided in no event shall such reduction(s) reduce the royalties otherwise payable to THERAVANCE during any Calendar Year by more than [***], and provided further than amounts not deducted in accordance with this Section 1.06 shall be carried forward to the following Calendar Year until [***] of all such amounts is so deducted.

(b) Combination Products. For Combination Licensed Products, the Parties shall meet prior to beginning clinical Development of such Combination Licensed Product, and negotiate in good faith appropriate adjustments to the Royalty and share of Operating Profits (Loss) for THERAVANCE to receive, based on the relative value of: 1) the Parties' respective contributions to the Development and Commercialization (including associated expenses) of such Combination Licensed Product; and 2) relative importance and proprietary protection of the Stand Alone Licensed Product and the other active ingredient(s) included in such Combination Licensed Product. In the event the Parties are unable to agree with respect to such adjustments, Operating Profits (Losses) or Royalties, as applicable shall be multiplied by the fraction equal to 1/[the number of active ingredients in such Combination Licensed Product].

Section 1.07 Reporting and Payment.

(a) Reports.

(i) On or before the tenth (10_{th}) day of each month, each Party will provide a written report to the other Party setting forth, with respect to THERAVANCE, the Development Expenses and, with respect to both Parties, the Operating Expenses, Shared Expenses and Patent expenses subject to reimbursement in accordance with Article 12 ("Reimbursable Patent Expenses"), incurred and anticipated to be incurred by such Party during the then-current Calendar Quarter and Calendar Year. Such reports shall compare such amounts to the amounts set forth in the Development Budget or

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Commercial Budget, respectively, for the corresponding periods. Within fifteen (15) days after the end of each Calendar Quarter during the Term, THERAVANCE shall also provide to MYLAN a written report of its Operating Expenses, Shared Expenses and Reimbursable Patent Expenses incurred for such Calendar Quarter.

(ii) As soon as is reasonably practical after the end of each Calendar Quarter, MYLAN shall submit to THERAVANCE a written report (each, a "Quarterly Report") setting forth in reasonable detail for such Calendar Quarter (i) Net Sales in the Territory, in the aggregate and on a country-by-country basis, (ii) Royalties owed to THERAVANCE on ROW Net Sales, (iii) COGS for the U.S., (iv) Operating Expenses and Shared Expenses for the Calendar Quarter, incurred by each Party and in the aggregate, (v) Operating Profit (Loss) and each Party's share thereof, (vi) Reimbursable Patent Expenses and each Party's share thereof, and (vii) the amounts due to or from the relevant Party, as well as the computation of each of the foregoing.

(iii) Subject to Section 1.07(b) below, within fifteen (15) days following submission to THERAVANCE of each Quarterly Report, the Parties shall make any reconciling payments necessary to effect the Royalties owed to THERAVANCE pursuant to Section 1.04 of this Exhibit F, and the sharing of Operating Expense and Operating Profit (Loss) of the Parties set forth in Section 1.03 of this Exhibit F for such Calendar Quarter. For clarity, if the amount of the Operating Profits (Loss) are negative with respect to any Calendar Quarter, the Parties will share such Operating Loss and THERAVANCE will make any necessary payments to MYLAN.

(iv) The reports required by this Section 1.07 shall be the reporting Party's Confidential Information subject to the protections of Article 9 of the Agreement.

(b) Disputes**.** In the event of a dispute regarding any amount reported by a Party or any amount owed under Section 1.07(a) above, 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 sixty (60) days after notice by the disputing Party, the Parties will (a) use reasonable, good faith efforts to reach agreement on the appointment of one internationally-recognized independent accounting firm to determine the matter or (b) if the Parties cannot reach agreement on such accounting firm, then the head of the office of the American Arbitration Association in New York City shall choose an internationally-recognized independent accounting firm to make the final determination.

(c) Efforts to Streamline Reporting. The Parties will cooperate in good faith to develop processes and align the reporting timelines set forth in this Section 1.07 with each Party's internal close calendars and internal and other reporting obligations.

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EXHIBIT G
Share Purchase Agreement
(See Attached)

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EXHIBIT H

Change of Control Conflict Companies

[***]

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EXHIBIT I

Approved Manufacturers

The JSC shall not withhold its approval of the following Commercial manufacturers:
[***]
The JSC shall not withhold its approval of the following manufacturers for supply of Licensed Product for use in the clinical trials included in the Preliminary Development Plan:
[***]
The JSC shall not withhold its approval of the following manufacturers for supply of API for use in the clinical trials included in the Preliminary Development Plan:
[***]
Notwithstanding the foregoing, MYLAN shall have the right to conduct a quality inspection of the foregoing manufacturers of the Licensed Product or API Compound or any component of the Licensed Product for use in the clinical trials included in the Preliminary Development Plan in accordance with Section 7.01(a), and the JSC may withhold or withdraw its approval of such manufacturers in the event any such inspection reveals material quality issues.

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Exhibit 10.60
Execution Copy
CONFIDENTIAL

LICENSE AND COLLABORATION AGREEMENT

by and between

THERAVANCE BIOPHARMA IRELAND LIMITED,

and

JANSSEN BIOTECH, INC.

Dated as of February 5, 2018

TABLE OF CONTENTS

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(cont'd)

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

LICENSE AND COLLABORATION AGREEMENT

This **LICENSE AND COLLABORATION AGREEMENT** (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.

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 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).

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.

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

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

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.

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.

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.

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.

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.

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

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.

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.

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.

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

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

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.

Defined Terms	Sections
[***]	2.5(a)
Additional Compound Notice	2.5(a)
Agreement	Preamble
Alliance Manager	3.4
Allowable Expenses	Exhibit M
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)
[***]	Exhibit M
Claims	9.1
Clearances	2.2
CMC Budget	4.2(c)(vi)
Code	13.3(a)
COGS	Exhibit M
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	Exhibit M
Cost Variances	Exhibit M
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
[***]	Exhibit M
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

Foreign Authorities	2.2
FTC	2.2
[***]	Exhibit M
[***]	Exhibit M
[***]	Exhibit M
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)
[***]	Exhibit M
[***]	Exhibit M
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
[***]	Exhibit M
Other Costs Not Included in Standard	Exhibit M
Other Income	Exhibit M
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	Exhibit M
Pre-Opt-In Phase 3 Activities	4.2(b)(ii)
Product Marks	7.8
Profit (Loss)	Exhibit M

Quarterly Report	6.9(b)
[***]	Exhibit M
Receiving Party	6.9(d)
Recording Party	6.13
Royalty Term	6.8(b)
Second Opt-In Fee	2.5(b)(ii)
[***]	Exhibit M
[***]	Exhibit M
[***]	Exhibit M
[***]	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	Exhibit M
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)
[***]	Exhibit M
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

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.

(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

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.

(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

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.

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

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

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

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.

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

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

(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).

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

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

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.

(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).

(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

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.

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

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

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

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-

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.

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

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

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

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.

Development Milestone Event	**Milestone Payment for First Primary Indication**	**Milestone Payment for Other Primary Indication**	**Milestone Payment for Other Indication**
[***] ("Milestone 1")	[***]	[***]	[***]
[***] ("Milestone 2")	[***]	[***]	[***]

[***]. 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

[***]. 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 [***]	[***]

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

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

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

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.

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

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.

(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.

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

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.

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

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

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.

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

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.

(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.

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

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,

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.

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.

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

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

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, 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, 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

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 [***].

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

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

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, [***].

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.

(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

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.

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) 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), 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

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

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.

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

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.

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}

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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[***]

[***]

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EXHIBIT F
INITIAL CMC DEVELOPMENT PLAN

1. Overview

[***]

2. Dose Assumptions for Clinical Studies

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3. Manufacturing Plans

[***]
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4. Phase 3 Development Plans

[***]

[***]
[***]

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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.

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.

EXHIBIT L

J&J UNIVERSAL CALENDAR

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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,

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.

"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.

EXHIBIT N
SOLAR PATENT RIGHTS

[***]
[***]

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.

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.

Subsidiaries

Theravance Biopharma US, Inc. (Delaware)

Theravance Biopharma UK Limited (England and Wales)

Theravance Biopharma Ireland Limited (Ireland)

Theravance Biopharma R&D IP, LLC (Delaware)

Theravance Biopharma Antibiotics IP, LLC (Delaware)

Theravance Biopharma US Holdings, Inc. (Delaware)

Triple Royalty Sub LLC (Delaware)

Triple Royalty Sub II LLC (Delaware)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-8 Nos. 333-198206, 333-202856, 333-210225, 333-216446, 333-223470, and 333-231559) pertaining to the Theravance Biopharma, Inc. 2013 Equity Incentive Plan and the Theravance Biopharma, Inc. 2013 Employee Share Purchase Plan,

(2) Registration Statement (Form S-8 No. 333-200225) pertaining to the Theravance Biopharma, Inc. 2014 New Employee Equity Incentive Plan, and

(3) Registration Statement (Form S-3 No. 333-235339) of Theravance Biopharma, Inc.;

of our reports dated February 26, 2021, with respect to the consolidated financial statements of Theravance Biopharma, Inc. and the effectiveness of internal control over financial reporting of Theravance Biopharma, Inc., included in this Annual Report (Form 10-K) of Theravance Biopharma, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
February 26, 2021

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Rick E Winningham, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 periods 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 periods in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods 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.

February 26, 2021
(Date)

/s/ RICK E WINNINGHAM
Rick E Winningham
Chairman of the Board and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Andrew Hindman, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 periods 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 periods in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the periods 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.

February 26, 2021
(Date)

/s/ Andrew Hindman
Andrew Hindman
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Theravance Biopharma, Inc. on Form 10-K for the fiscal year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. for the periods covered by such Annual Report on Form 10-K and results of operations of Theravance Biopharma, Inc. for the periods covered by such Annual Report on Form 10-K.

February 26, 2021
(Date)

By: /s/ Rick E Winningham
Name: Rick E Winningham
Title: *Chairman of the Board and Chief Executive Officer*
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Hindman, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Theravance Biopharma, Inc. on Form 10-K for the fiscal year ended December 31, 2020 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition of Theravance Biopharma, Inc. for the periods covered by such Annual Report on Form 10-K and results of operations of Theravance Biopharma, Inc. for the periods covered by such Annual Report on Form 10-K.

February 26, 2021
(Date)

By: /s/ Andrew Hindman
Name: Andrew Hindman
Title: *Senior Vice President and Chief Financial Officer*
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Theravance Biopharma, Inc. and will be retained by it and furnished to the Securities and Exchange Commission or its staff upon request.