Innoviva, Inc.
Form 10-K
February 19, 2019

Use these links to rapidly review the document

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

o **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. 000-30319

INNOVIVA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3265960**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2000 Sierra Point Parkway, Suite 500 Brisbane, CA	**94005**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 238-9600**

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

Title of Each Class	**Name of Each Exchange On Which Registered**
Common Stock $0.01 Par Value	The Nasdaq Stock Market LLC

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 ý No o

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 o No ý

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 ý No o

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 ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o
			Emerging growth company o

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. o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's Common Stock on The Nasdaq Global Select Market on June 29, 2018 was $904,845,424. This calculation does not reflect a determination that persons are affiliates for any other purpose.

On February 11, 2019, there were 101,123,024 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2019 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2018, 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.

Table of Contents

INNOVIVA, INC.
2018 Form 10-K Annual Report

Table of Contents

Table of Contents

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, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Securities Act"). Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Annual Report on Form 10-K, other than statements of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words "anticipates," "believes," "could," "designed," "estimates," "expects," "goal," "intends," "may," "objective," "plans," "projects," "pursuing," "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. 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. All written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Important factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the company (including the company's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner and amount of potential capital returns to stockholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; projections of revenue, expenses and other financial items and risks discussed below in "Risk Factors" in Item 1A of Part I, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II 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 as of the date hereof and we do not assume any obligation to update any forward-looking statements on account of new information, future events or otherwise, except as required by law.

We encourage you to read Management's Discussion and Analysis of our Financial Condition and Results of Operations and our consolidated financial statements contained in this Annual Report on Form 10-K. We also encourage you to read Item 1A of Part I of this Annual Report on Form 10-K, entitled "Risk Factors," which contains a more complete discussion of the risks and uncertainties associated with our business. In addition to the risks described above and in Item 1A of this report, other unknown or unpredictable factors also could affect our results. Therefore, the information in this report should be read together with other reports and documents that we file with the Securities and Exchange Commission ("SEC") from time to time, including on Form 10-Q and Form 8-K, which may supplement, modify, supersede or update those risk factors. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Table of Contents

PART I

ITEM 1. BUSINESS

Overview

Innoviva, Inc. ("Innoviva", the "Company", the "Registrant" or "we" and other similar pronouns) is focused on royalty management. Innoviva's portfolio includes the respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI"), ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI") and TRELEGY® ELLIPTA® (the combination FF/UMEC/VI). Under the Long-Acting Beta2 Agonist ("LABA") Collaboration Agreement, Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion; and royalties from the sales of ANORO® ELLIPTA®, which tier upward at a range from 6.5% to 10%. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), including TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered or developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Our headquarters are located at 2000 Sierra Point Parkway, Suite 500, Brisbane, CA 94005. The Company was incorporated in Delaware in November 1996 under the name Advanced Medicine, Inc., and began operations in May 1997. It later changed its name to Theravance, Inc. in April 2002. In June 2014, we spun-off our research and development operations. In January 2016, we rebranded and changed our name to Innoviva, Inc.

Our Strategy

Our corporate strategy is currently focused on the goal of maximizing stockholder value by, among other things, maximizing the potential value of our respiratory assets partnered with GSK and optimizing our operations and capital allocation.

Our Relationship with GSK

LABA Collaboration

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily products for the treatment of chronic obstructive pulmonary disease ("COPD") and asthma. The collaboration has developed three combination products:

RELVAR®/BREO® ELLIPTA® ("FF/VI") (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol ("VI"), and an inhaled corticosteroid ("ICS"), fluticasone furoate ("FF"),

ANORO® ELLIPTA® ("UMEC/VI"), a once-daily medicine combining a long-acting muscarinic antagonist ("LAMA"), umeclidinium bromide ("UMEC"), with a LABA, VI, and

TRELEGY® ELLIPTA® (the combination FF/UMEC/VI), a once-daily combination medicine consisting of an ICS, LAMA and LABA.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, in accordance with the LABA Collaboration Agreement, we paid milestone fees to GSK totaling $220.0 million during the year ended December 31, 2014. The

Table of Contents

milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the products.

2004 Strategic Alliance

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on predetermined terms and on an exclusive, worldwide basis. In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Innoviva-discovered preclinical MABA compounds (the "Additional MABAs"). The development program was funded in full by GSK. GSK is in the process of determining the next steps for the program. As a result of the transactions effected by the spin-off of Theravance Biopharma in June 2014 (the "Spin-Off"), we are only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of products that may be developed under the Strategic Alliance Agreement, such as MABA, and MABA/FF, while Theravance Biopharma receives 85% of those same payments.

Common Stock owned by GSK

As of February 11, 2019, GSK beneficially owned approximately 31.7% of our outstanding common stock.

Recent Highlights

GSK Net Sales:

Fourth quarter 2018 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $431.6 million, up 7% from $405.3 million in the fourth quarter of 2017, with $236.4 million in net sales from the U.S. market and $195.2 million from non-U.S. markets.

Fourth quarter 2018 net sales of ANORO® ELLIPTA® by GSK were $186.2 million, up 26% from $147.3 million in the fourth quarter of 2017, with $125.7 million net sales from the U.S. market and $60.5 million from non-U.S. markets.

Fourth quarter 2018 net sales of TRELEGY® ELLIPTA by GSK were $99.0 million with $75.8 million in net sales from the U.S. market and $23.2 million in net sales from non-U.S. markets. TRELEGY® ELLIPTA® was approved in the U.S. in September 2017.

Product Updates:

In November 2018, the European Commission authorized an expanded label of TRELEGY® ELLIPTA® (the combination FF/UMEC/VI) for once daily use in patients with moderate to severe COPD not adequately treated with dual bronchodilators or with an ICS and a LABA.

Manufacturing

Manufacturing of RELVAR®/BREO® ELLIPTA® (FF/VI), ANORO® ELLIPTA® (UMEC/VI) and TRELEGY® ELLIPTA® is performed by GSK.

Government Regulation

The development and commercialization of products and product candidates pursuant to the GSK Agreements are subject to extensive regulation by governmental authorities in the United States and other countries. Before marketing in the United States, any medicine must undergo rigorous preclinical studies and clinical studies and an extensive regulatory approval process implemented by the FDA.

Table of Contents

Outside the United States, the ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical studies, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, the commercialization of medicines is permitted only if the appropriate regulatory authority is satisfied that our collaborative partner has presented adequate evidence of the safety, quality and efficacy of such medicines.

Once a product is approved, the FDA may withdraw the product approval if compliance with pre- and 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, referred to as Phase 4 studies, to monitor the effect 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 institute criminal prosecution.

If regulatory approval for a medicine is obtained, the clearance to market the product will be limited to those diseases and conditions for which the medicine is effective, as demonstrated through clinical studies and included 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 and our collaborative partner 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 the development and commercialization of products and product candidates. 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 institute 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 United States, our collaborative partner's ability to market partnered products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. Risks similar to those associated with FDA approval and continuing review described above exist with the regulatory approval processes in other countries.

Patents and Proprietary Rights

We and our collaborative partner will be able to protect our partnered technology from unauthorized use by third parties only to the extent that such 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 us and our collaborative partner obtaining patent protection for our partnered products and product candidates. Accordingly, patents and other proprietary rights are essential elements 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 business that involve proprietary know-how and technology that is not covered by patent applications, we rely on trade secret protection and confidentiality agreements

Table of Contents

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, 2018, we owned 38 issued United States patents and 257 granted foreign patents, as well as additional pending United States patent applications and foreign patent applications. The claims in these various patents and patent applications are directed to compositions of matter, including claims covering product candidates, lead compounds and key intermediates, pharmaceutical compositions, methods of use and processes for making our compounds.

United States issued patents and foreign patents generally expire 20 years after filing. 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

We anticipate that RELVAR®/BREO®ELLIPTA®(FF/VI), ANORO® ELLIPTA® (UMEC/VI) and TRELEGY® ELLIPTA® (the combination FF/UMEC/VI) will compete with a number of approved bronchodilator drugs, including each other and drug candidates under development that are designed to treat asthma and COPD. These include but are not limited to:

Advair®/Seretide Diskus®/HFA® (salmeterol and fluticasone propionate as a combination) marketed by GSK,

Symbicort® (formoterol and budesonide as a combination) marketed by AstraZeneca,

AirDuo Respiclick® (salmeterol and fluticasone propionate), a non-substitutable generic version of Advair, marketed by TEVA,

Spiriva® Handihaler® and Spiriva Respimat® (tiotropium) marketed by Boehringer Ingelheim,

Dulera® (formoterol and mometasone as a combination) marketed by Merck,

Tudorza® Pressair® (aclidinium) marketed by AstraZeneca and Seebri® Breezehaler® (glycopyrronium) marketed by Novartis outside the U.S. and Sunovion in the U.S.,

Incruse® Ellipta® (umeclidinium) and Arnuity® Ellipta® (fluticasone furoate), (we are not entitled to any royalties from either product),

Foradil® Aerolizer® /Oxis® Turbuhaler® (formoterol) marketed by a number of companies,

Striverdi® Respimat® (olodaterol) marketed by Boehringer Ingelheim,

Onbrez® Breezehaler® (E.U.)/Arcapta® Neohaler® (U.S.) (indacaterol) marketed by Novartis,

Ultibro® Breezehaler® (E.U.)/Utibron® Neohaler® (U.S.), (indacaterol combined with the LAMA glycopyrronium bromide) developed by Novartis and approved and launched in Europe and Japan in the year ended December 31, 2013 as a once-daily treatment for COPD. In the U.S., the product was approved in October 2015 at a lower strength and as a twice-daily COPD treatment, and was licensed to Sunovion in December 2016, and launched in May 2017,

Table of Contents

Stiolto (U.S.)/Spiolto (E.U.) Respimat® consists of the LAMA tiotropium combined with the LABA olodaterol, marketed by Boehringer Ingelheim for the treatment of COPD,

Bevespi Aerosphere® (consisting of the LAMA glycopyrronium bromide and the LABA formoterol fumarate), marketed by AstraZeneca,

Duaklir® Genuair® (consisting of the LAMA aclidinium bromide and LABA formoterol fumarate), developed by AstraZeneca and approved in November 2014 in the EU as a maintenance bronchodilator treatment for COPD,

QMF149, indacaterol in combination with an ICS (mometasone), being developed by Novartis for markets outside the U.S.,

Trimbow, a fixed-dose, twice daily combination of formoterol, beclomethasone and glycopyrronium manufactured by Chiesi of Italy and indicated for use in COPD, became the first triple therapy/single inhaler product in Europe, launched four months ahead of TRELEGY,

QVM149, a fixed-dose combination of indacaterol, mometasone and glycopyrronium is in Phase 3 clinical development by Novartis as a triple therapy/single inhaler for the treatment of asthma,

PT010, a fixed dose combination of formoterol, glycopyrronium and budesonide being developed by AstraZeneca as a triple therapy single inhaler twice-daily medication for COPD,

QAW039 (fevipiprant), an orally active once-daily prostaglandin D2 inhibitor in Phase 3 development by Novartis for the treatment of asthma, and

Dupixent (dupilamab), an injectable IL-4 and IL-13 inhibitor developed by Sanofi Genzyme and approved by the FDA in October 2018 as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.

In addition, several firms are developing new formulations of Advair/Seretide (salmeterol /fluticasone propionate) and Symbicort (formoterol fumerate/budesonide) which may be marketed as generics or branded generics relative to the existing products from GSK and AstraZeneca, respectively. All of these efforts represent potential competition for any of our partnered products. Efforts have intensified following the publication of FDA draft guidance for the approval of fully substitutable versions of Advair and Symbicort in late 2013 and mid-2015, respectively. Current examples of these products include the marketed products Duoresp/Biresp from Teva (generic Symbicort), AirFluSal Forspiro by Sandoz, Rolenium by Elpen and Sirdupla by Mylan (all generic versions of Seretide) which are all available in a wide number of countries in the E.U. Numerous companies like Mylan N.V., Hikma Pharmaceuticals PLC (Hikma), Novartis' Sandoz division and Teva Pharmaceuticals Industries Ltd. (Teva) have publicly stated their intentions to bring generic forms of the ICS/LABA drug Advair®, when certain patents covering the Advair® delivery device expired in 2016. In March 2017, Mylan N.V. received a complete response letter from the FDA relating to its Abbreviated New Drug Application ("ANDA") for fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder. In May 2017, Hikma announced that it received a complete response letter from the FDA relating to its ANDA for fluticasone propionate and salmeterol inhalation powder, and in February 2018, Novartis announced that its generic division Sandoz had received a complete response letter from the FDA in response to its ANDA for a third fluticasone propionate and salmeterol product. In January 2019, Mylan announced that the FDA approved Wixela Inhu (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of ADVAIR DISKUS®. Lastly, Teva announced recently that the FDA approved two of its products for adolescent and adult patients with asthma, one of which is AirDuo RespiClick® (fluticasone propionate and salmeterol inhalation powder), a non-AB substitutable generic version of Advair®. In general, these manufacturers are required to conduct a restricted number of clinical efficacy, pharmacokinetic and device studies to

Table of Contents

demonstrate equivalence to Advair, per the FDA's September 2013 Draft Guidance Document. These studies are designed to demonstrate that the generic product has the same active ingredient(s), dosage form, strength, exposure and clinical efficacy as the branded product. These generic equivalents, which must meet the same exacting quality standards as branded products, may be significantly less costly to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product and products that may compete with such branded product is typically lost to the generic product. In addition, in April 2016, the FDA issued draft guidelines documents covering Fluticasone Furoate/Vilanterol Trifenatate (FF/VI), the active ingredients used in RELVAR®/BREO® ELLIPTA®.

Employees

As of December 31, 2018, we had six employees. None of our employees are represented by a labor union. We consider our employee relations to be good.

Executive Officers of the Registrant

The following table sets forth the name, age, and position of each of our executive officers as of February 19, 2019:

Name	Age	Positions Held
Geoffrey Hulme	52	Interim Principal Executive Officer
Marianne Zhen	50	Chief Accounting Officer

Geoffrey Hulme was appointed Interim Principal Executive Officer in May 2018. Prior to his hiring, Mr. Hulme served as the owner and manager of Steel Valley Capital LLC since 2016 and Steel Valley Advisors LLC, a registered investment adviser, since 2017. Previously, from 1998 to 2015, he worked at Amici Capital, LLC, serving in various roles, including as Director of Research, a portfolio manager and a director of various funds managed by Amici. Mr. Hulme earned a Bachelor of Science degree in Business Administration with a concentration in Finance, summa cum laude, from Villanova University.

Marianne Zhen was appointed Chief Accounting Officer in July 2018. Ms. Zhen joined Innoviva in October 2014 as Corporate Controller. Prior to joining Innoviva, Ms. Zhen served as the Corporate Controller at Steelwedge Software Inc. from 2012 to 2014, Intelmate from 2011 to 2012 and Model N, Inc. from 2007 to 2011. Ms. Zhen earned a Bachelor of Science degree in Business Administration with a concentration in Accounting from San Francisco State University. She is a Certified Public Accountant and a member of the American Institute of Certified Public Accountants.

Code of Business Conduct

The Company has adopted the Innoviva, Inc. Code of Business Conduct that applies to all directors, officers and employees. The Code of Business Conduct, as amended and restated on May 1, 2017, is available on the corporate governance section of our website at *www.inva.com*. If the Company makes any substantive amendments to the Code of Business Conduct or grants a waiver from any provision of such code to any executive officer or director, the Company will promptly disclose the nature of the amendment or waiver, as required by applicable law.

Available Information

Our web page address is *www.inva.com*. Our investor relations website is located at *http://investor.inva.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 after filing or furnishing such materials to the SEC. The information found on our website is not part of this or any other report that we file with or furnish to the SEC. Innoviva and the Innoviva logo are registered trademarks of Innoviva, Inc. Trademarks, tradenames or service marks of other companies appearing in this report are the property of their respective owners.

Table of Contents

ITEM 1A. RISK FACTORS

Risks Related to our Business

For the foreseeable future we will derive all of our royalty revenues from GSK and our future success depends on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK.

Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Royalty revenues from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are expected to represent the majority of our foreseeable future revenues from GSK. The amount and timing of revenue from such royalties are unknown and highly uncertain. Our future success depends upon the performance by GSK of its commercial obligations under the GSK Agreements and the commercial success of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and cause the price of our securities to fall.

Our quarterly royalty revenues may fluctuate due to a variety of factors, many of which are outside of our control. The amount of royalties and milestone payments, if any, we receive will depend on many factors, including the following:

- the extent and effectiveness of the sales and marketing and distribution support GSK provides to our partnered products;
- market acceptance and demand for our partnered products;
- changes in the treatment paradigm or standard of care for COPD or asthma, for instance through changes to the GOLD (Global Initiative for Chronic Obstructive Lung Disease) guidelines;
- the competitive landscape of generic and branded products and developing therapies that compete with our partnered products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;
- the size of the market for our partnered products;
- the mix of sales of our partnered products;
- decisions as to the timing of product launches, pricing and discounts;
- reprioritization of GSK's commercial efforts on other products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®), which are not partnered with us;
- GSK's ability to expand the indications for which our partnered products can be marketed;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;

timing and amounts of payor rebate adjustments and prior period rebate adjustments;

seasonal fluctuations of demand;

the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;

Table of Contents

safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular;

regulatory developments relating to the manufacture or continued use of our partnered products;

the requirement to conduct additional post-approval studies or trials for our partnered products;

decisions by GSK with respect to the MABA program;

GSK's ability to obtain regulatory approval of our partnered products in additional countries;

the unfavorable outcome of any potential litigation relating to our partnered products;

general economic conditions in the jurisdictions where our partnered products are sold, including microeconomic disruptions or slowdowns; or

if our royalty revenue or operating results fall below the expectations of investors or securities analysts or below any guidance we may provide to the market, the price of our common stock could decline substantially.

If the FDA or other applicable regulatory authorities approve generic products, including but not limited to generic forms of Advair®, that compete with RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, or generic form of RELVAR®/BREO® ELLIPTA®, the royalties payable to us pursuant to the LABA Collaboration Agreement will be less than anticipated, which in turn would harm our business and the price of our securities could fall.

Once an NDA or marketing authorization application outside the United States is approved, the product covered thereby becomes a "listed drug" that can, in turn, be cited by potential competitors in support of approval of an ANDA in the United States. Agency regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes in the United States and in nearly every pharmaceutical market around the world. Numerous companies like Mylan N.V., Hikma, Novartis' Sandoz division and Teva have publicly stated their intentions to bring generic forms of the ICS/LABA drug Advair®, when certain patents covering the Advair® delivery device expired in 2016. In January 2019, Mylan announced that the FDA approved Wixela Inhu (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of ADVAIR DISKUS®. In May 2017, Hikma announced that it received a complete response letter from the FDA relating to its ANDA for fluticasone propionate and salmeterol inhalation powder, and in February 2018, Novartis announced that its generic division Sandoz, had received a complete response letter from the FDA in response to its ANDA for a third fluticasone propionate and salmeterol product. Lastly, Teva announced recently that the FDA approved two of their products for adolescent and adult patients with asthma, one of which is AirDuo RespiClick® (fluticasone propionate and salmeterol inhalation powder), a non-AB substitutable generic version of Advair®. In general, these manufactures are required to conduct a restricted number of clinical efficacy, pharmacokinetic and device studies to demonstrate equivalence to Advair, per FDA's September 2013 Draft Guidance Document. These studies are designed to demonstrate that the generic product has the same active ingredient(s), dosage form, strength, exposure and clinical efficacy as the branded product. These generic equivalents, which must meet the same exacting quality standards as branded products, may be significantly less costly to bring to market, and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product and products that may compete with such branded product is typically lost to the generic product. In addition, in April 2016, the FDA issued draft guidelines documents covering Fluticasone Furoate/Vilanterol Trifenatate (FF/VI), the active ingredients used in RELVAR®/BREO® ELLIPTA®. Accordingly, introduction of generic products that compete against ICS/LABA products, like RELVAR®/BREO® ELLIPTA®, would materially

Table of Contents

adversely impact our future royalty revenue, profitability and cash flows. We cannot yet ascertain what impact these generic products and any future approved generic products will have on any sales of RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA®, if approved.

Reduced prices and reimbursement rates due to the actions of governments, payors, or competition or other healthcare cost containment initiatives such as restrictions on use, may negatively impact royalties generated under the GSK Agreements.

The continuing efforts of governments, pharmaceutical benefit management organizations ("PBMs"), insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care has adversely affected the price, market access, and total revenues of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and TRELEGY® ELLIPTA® and may continue to adversely affect them in the future. In addition, we have experienced and expect to continue to experience increased competitive activity, which has resulted in lower overall prices for our products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, "PPACA") and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U.S., could adversely influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK's ability to market our partnered products and significantly reduce future revenues. For example, when GSK launched BREO® ELLIPTA® for the treatment of COPD in the U.S. in October 2013, GSK experienced significant challenges gaining coverage at some of the largest PBMs, healthcare payors, and providers and lower overall prices than expected. Recent actions by U.S. PBMs in particular have increased discount levels for respiratory products resulting in lower net sales pricing realized for products in our collaboration. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures will continue and may increase. This may make it difficult for GSK to sell our partnered products at a price acceptable to us or GSK or to generate revenues in line with our analysts' or investors' expectations, which may cause the price of our securities to fall.

More recently, the current presidential administration and the U.S. Congress have taken actions in an effort to replace PPACA and related legislation with new healthcare legislation. There is uncertainty with respect to the impact these potential changes may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures, and may adversely affect our operating results.

Our current revenues are from royalties derived from sales of our respiratory products partnered with GSK, RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and TRELEGY® ELLIPTA®. If the treatment paradigm for the indications our partnered products are approved for change or if GSK is unable to, or does not devote sufficient resources to, maintain or continue increasing sales of these products, our results of operations will be adversely affected.

We currently depend on royalties from sales of our products partnered with GSK to support our existing operations. The treatment paradigm for COPD and asthma constantly evolve. For instance, in

Table of Contents

November 2018, the GOLD guidelines were revised to favorably position bronchodilator monotherapy and LABA/LAMA treatment ahead of ICS/LABA for the treatment of COPD unless the patient has frequent exacerbations or an eosinophil count greater than 300 per cubic microliter. The use of ICS in COPD is also recommended for patients requiring triple therapy (LABA, LAMA, ICS). If the treatment paradigms were to change further, causing our partnered products to fall out of favor, or if GSK were unable, or did not devote sufficient resources, to maintain or continue increasing RELVAR®/ BREO® ELLIPTA® and ANORO® ELLIPTA® sales, our results of operations would likely suffer and we might need to scale back our operations.

If the commercialization of RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® in the countries in which they have received regulatory approval encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage does not meet investors', analysts', or our expectations, our business will be harmed, and the price of our securities could fall.

Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of RELVAR®/ BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA®. GSK has launched RELVAR®/ BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® in a number of countries, including the United States, Canada, Japan, the United Kingdom, and Germany, among others. The commercialization of the products in countries where they are already launched and the commercialization launch in new countries are still subject to fluctuating overall pricing levels and uncertain timeframes to obtain payor coverage. Any delays or adverse developments or perceived additional delays or adverse developments with respect to the commercialization of RELVAR®/ BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA® including if sales or payor coverage does not meet investors', analysts', or our expectations, would significantly harm our business and the price of our securities could fall.

We are dependent on GSK for the successful commercialization and development of products under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization or development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, including TRELEGY® ELLIPTA®, our business would be materially harmed.

GSK is responsible for all clinical and other product development, regulatory, manufacturing and commercialization activities for products developed under the GSK Agreements, including RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®. Our royalty revenues under the GSK Agreements may not meet our, analysts', or investors' expectations, due to a number of important factors. GSK has a substantial respiratory product portfolio in addition to the partnered products that are 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 us. For instance, GSK has wide discretion in determining the efforts and resources that it will apply to the development and commercialization of our partnered products. GSK is currently evaluating the next steps with respect to the MABA program. In the event that GSK terminates this or any other development program (other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®) pursuant to agreements entered into in connection with the Spin-Off, the right to such programs would revert to Theravance Biopharma. The timing and amount of royalties that we may receive will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of these product candidates by GSK. In addition, GSK may determine to focus its commercialization efforts on its own products or TRELEGY® ELLIPTA®. For example, in January 2015, GSK launched Incruse® (UMEC) in the U.S., which is a LAMA for the treatment of COPD. GSK may determine to focus its marketing efforts on Incruse, which could have the effect of decreasing the potential market share of ANORO® ELLIPTA® and lowering the royalties we may receive for such product. Alternatively, GSK may decide to market

Table of Contents

TRELEGY® ELLIPTA® to eventually compete directly against sales of RELVAR®/BREO® ELLIPTA®. Following the FDA approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations regarding commercialization matters now have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval are guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. If GSK prioritizes TRELEGY® ELLIPTA®, we will only be entitled to a 15% economic interest of the royalties paid pursuant to the GSK Agreements with respect to this product. In the event GSK does not devote sufficient resources to the development or commercialization of our partnered products or chooses to reprioritize its commercial programs, our business, operations and stock price would be negatively affected.

Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma could significantly harm our royalty revenues and the price of our securities could fall.

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and it will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as "clinical trial design") to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it required the manufacturers of currently marketed LABAs to conduct additional randomized, double blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. These post-marketing studies have been completed and did not show an increased risk of use of ICS/LABA compared to ICS alone. The FDA subsequently removed the black box warning from the ICS/LABA package inserts. Although this concern appears to be resolved, it is unknown at this time what, if any, future concerns could impact the use of ICS/LABA and its potential impact on the prospects for FF/VI. Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma could significantly harm our business and the price of our securities could fall.

Any adverse developments to the regulatory status of either RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® in the countries in which they have received regulatory approval, including labeling restrictions, safety findings, or any other limitation to usage, would harm our business and may cause the price of our securities to fall.

Although RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® or TRELEGY® ELLIPTA® are approved and marketed in a number of countries, it is possible that adverse changes to the regulatory status of these products could occur in the event new safety issues are identified, treatment guidelines are changed, or new studies fail to demonstrate product benefits. A number of notable pharmaceutical products have experienced adverse developments during commercialization that have resulted in the product being withdrawn, approved uses being limited, or new warnings being included. In the event that any adverse regulatory change were to occur to any of our products, our business would be harmed and the price of our securities could fall.

Table of Contents

Any adverse developments or results or perceived adverse developments or results with respect to the ongoing studies for FF/VI in asthma or COPD, for UMEC/VI in COPD, or any future studies would significantly harm our business and the price of our securities could fall, and if regulatory authorities in those countries in which approval has not yet been granted determine that the ongoing studies for FF/VI in asthma or COPD or the ongoing studies for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both could be significantly delayed, they might not be approved by these regulatory authorities, and even if approved they may be subject to restrictive labeling, any of which might harm our business, and the price of our securities could fall.

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, additional studies of FF/VI are underway or may commence in the future. Any adverse developments or perceived adverse developments with respect to any prior, current or future studies in these programs could significantly harm our business and the price of our securities could fall. For example, in September 2015, GSK and we announced that the Study to Understand Mortality and MorbidITy (SUMMIT) did not meet its primary endpoints, which resulted in a significant decline in the price of our stock.

Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada and other jurisdictions have approved ANORO® ELLIPTA®, it has not yet been approved in all jurisdictions.

Any adverse developments or results or perceived adverse developments or results with respect to other pending or future regulatory submissions for the FF/VI program or the UMEC/VI program might significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;
- analysts adjusting their sales forecasts downward from previous projections based on results or interpretations of results of prior, current or future studies;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs;
- regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or
- any change in FDA (or comparable foreign regulatory agency) policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the LABA Collaboration Agreement to be less than expected, which in turn would harm our business and cause the price of our securities to fall.

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the U.S. and certain other targeted markets, the products face substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new

Table of Contents

products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®.

Many of the pharmaceutical companies competing in respiratory markets are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructure that facilitates commercializing their products in a highly efficient and low cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® to succeed and achieve the anticipated level of sales depends on the commercial and development performance of GSK to achieve and maintain a competitive advantage over other products with the same intended use in the targeted markets.

In addition, following the September 2017 FDA approval of TRELEGY® ELLIPTA®, GSK's diligent efforts obligations regarding commercialization matters has the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval are guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. GSK also received in April 2018 an expanded label approval for TRELEGY® ELLIPTA®, allowing it to be used by U.S. physicians as first line therapy in appropriate COPD patients. A similar expanded use label was granted by the European Medicines Agency in September 2018. Innoviva is only entitled to a 15% economic interest in the future payments made by GSK under the GSK Agreements with respect to this product.

If sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments could be less than anticipated, which in turn would harm our business and cause the price of our securities to fall.

We and GSK recently received regulatory approval in the U.S. and positive regulatory opinion in Europe for TRELEGY® ELLIPTA® as triple combination treatments for COPD. As a result of the Spin-Off, most of our economic rights in this program and other programs were assigned to Theravance Biopharma. If these programs are successful and GSK and the respiratory market in general views triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, our business could be harmed, and the price of our securities could fall.

The use of triple therapy is supported by the GOLD guidelines in symptomatic patients with severe COPD and a high risk of exacerbations. Prior to the Spin-Off, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. As a result of the transactions effected by the Spin-Off, however, we are now only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements which were assigned to TRC, while

Table of Contents

Theravance Biopharma receives 85% of those same payments. The commercial success of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® may be adversely affected if GSK or the respiratory markets view TRELEGY® ELLIPTA® or other combination therapies as more beneficial. GSK's diligent efforts obligations regarding commercialization matters have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval are guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future.

In the event that Theravance Biopharma defaults or breaches the agreements we entered into with them in connection with the Spin-Off, our business and results of operations could be materially harmed.

Upon the Spin-Off, our facility leases in South San Francisco, California were assigned to Theravance Biopharma. However, if Theravance Biopharma were to default on its lease obligations, we would be held liable by the landlord and thus we have in substance guaranteed the lease payments for these facilities. We would also be responsible for lease-related payments, including utilities, property taxes, and common area maintenance, which could be as much as the actual lease payments. As of December 31, 2018, the total remaining lease payments, which run through May 2020, were $9.3 million. In the event that Theravance Biopharma defaults on such obligations, our business and results of operations could be materially harmed.

Under the terms of a separation and distribution agreement entered into between us and Theravance Biopharma, Theravance Biopharma will indemnify us from (i) all debts, liabilities and obligations transferred to Theravance Biopharma in connection with the Spin-Off (including its 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 in its information statement filed with the SEC, resulting in a misleading statement and (iii) any breach by it of certain agreements entered into between the parties in connection with the Spin-Off. Theravance Biopharma's ability to satisfy these indemnities, if called upon to do so, will depend upon its future financial strength and if we are not able to collect on indemnification rights from Theravance Biopharma, our financial condition may be harmed.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (TCJA), was signed into law, significantly reforming the U.S. Internal Revenue Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits.

The TCJA is a complex revision to the U.S. federal income tax laws with disparate and, in some cases, countervailing impacts on different categories of taxpayers and industries, and will require subsequent rulemaking and interpretation in a number of areas. The long-term impact of the TCJA on the overall economy, the industries in which we operate and our and our partners business cannot be reliably predicted at this early stage of the new law's implementation. There can be no assurance that the TCJA will not negatively impact our operating results, financial condition, and future business operations. The estimated impact of the TCJA is based on our management's current knowledge and assumptions, following consultation with our tax advisors, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of common stock is uncertain and could be materially adverse.

Table of Contents

This Annual Report does not discuss any such tax legislation or the manner in which it might affect investors in common stock. Investors should consult with their own tax advisors with respect to such legislation and the potential tax consequences of investing in common stock.

We may not be able to utilize all of our net operating loss carryforwards.

We have net operating loss carryforwards and other significant U.S. tax attributes that we believe could offset otherwise taxable income in the U.S. As a part of the overall Spin-Off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as amended (the "Code") and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will generally equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we will not recognize any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service ("IRS"), which could result in an increase in the amount of gain realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. The net operating loss carryforwards available in any year to offset our net taxable income will be reduced following a more than 50% change in ownership during any period of 36 consecutive months (an "ownership change") as determined under the Code. Transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. We have conducted an analysis to determine whether an ownership change had occurred since inception through September 30, 2018, and concluded that we had undergone two ownership changes in prior years. Subsequent changes in our ownership or sale of our stock could have the effect of limiting the use of our net operating losses in the future. We have approximately $0.8 billion of net operating loss carryforward as of December 31, 2018. There may be certain annual limitations for utilization based on the above-described ownership change provisions. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. As a result of the passage of the TCJA, corporate tax rates in the United States decreased in 2018, which resulted in the remeasurement of our deferred tax assets at the new statutory rate and a reduction in the value of our deferred tax assets in 2017. Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

If any product candidates in any respiratory program partnered with GSK were not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business would be adversely affected and the price of our securities could fall.

The FDA must approve any new medicine before it can be marketed and sold in the U.S. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to

Table of Contents

market medicines in foreign countries, separate regulatory approvals must be obtained 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 country may make approval in other countries more difficult.

Clinical studies involving product candidates partnered with GSK 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 clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition could be materially harmed and the price of our securities might fall.

Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created a conservative regulatory environment. The implementation of new laws and regulations and revisions to FDA clinical trial design guidance have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of any product candidates in any respiratory program partnered with GSK.

Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and TRELEGY® ELLIPTA®, commercialization of such products may be adversely affected by regulatory actions and oversight.

Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products.

For example, at the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA regarding the sNDA for BREO® ELLIPTA® as a treatment for asthma, the advisory committee recommended that a large LABA safety trial with BREO® ELLIPTA® should be required in adults and in 12-17 year olds, similar to the ongoing LABA safety trials being conducted as an FDA Post-Marketing Requirement by each of the manufacturers of LABA containing asthma treatments. The FDA did not concur with the recommendation. A pediatric program including patients 5-17 years of age is currently ongoing.

Table of Contents

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we or GSK become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on GSK, including requiring it 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. GSK is also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies, as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Any failure to maintain regulatory approval would limit GSK's ability to commercialize the product candidates in any respiratory program partnered with GSK, which could materially and adversely affect our business and financial condition and which may cause the price of our securities to fall.

We may not be successful in our strategic efforts.

In the future, we may choose to acquire interests in or rights to one or more additional royalty-generating products. However, we may be unable to license or acquire rights to suitable royalty-generating products for a number of reasons. In particular, the licensing and acquisition of pharmaceutical product rights is a competitive area. Several more established companies are also pursuing strategies to license or acquire rights to royalty-generating products. These established companies may have a competitive advantage over us. Other factors that may prevent us from licensing or otherwise acquiring rights to suitable royalty-generating products include the following:

- we may be unable to license or acquire the rights on terms that would allow us to make an appropriate return from the product;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable royalty-generating products.

If we are unable to acquire or license rights to suitable royalty-generating product candidates, our business may suffer.

We may become engaged in a review of opportunities to acquire income generating assets, whether royalty-based or otherwise, or to acquire companies that hold royalty or other income generating assets. We currently, and generally at any time, have acquisition opportunities in various stages of active review. Also, we may engage consultants and advisors to analyze particular opportunities, technical, financial and other confidential information, submission of indications of interest and involvement as a bidder in competitive auctions or other processes for the acquisition of income generating assets. We may face significant competition for these acquisitions from other financial investors and enterprises whose cost of capital may be lower than ours. Competition for future asset acquisition opportunities in our markets is competitive and we may be forced to increase the price we pay for such assets or face reduced potential acquisition opportunities. The success of any potential income-generating asset acquisition is based on our ability to make accurate assumptions regarding the valuation, timing and amount of payments, which is highly complex and uncertain. The failure of any potential acquisition to

Table of Contents

produce anticipated revenues may materially and adversely affect our financial condition and results of operations.

We have a significant amount of debt including our term loan, convertible subordinated notes and convertible senior notes that are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our stockholders.

As of December 31, 2018, we had approximately $447.2 million in total debt outstanding, comprised primarily of $241.0 million in principal that remains outstanding under our convertible subordinated notes due 2023 (the "2023 Notes"), $192.5 million in principal outstanding under our convertible senior notes due 2025 (the "2025 Notes") (the 2023 Notes and 2025 Notes hereinafter, the "Notes") and $13.8 million in principal outstanding on our term B loan (the "Term B Loan"). The Notes are unsecured debt and are not redeemable by us prior to the maturity date. Holders of the 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. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock, and, under the 2023 Notes, the change of a majority of our Board of Directors without the approval of the Board of Directors. In addition, to the extent we pursue and complete a monetization transaction or a transaction that modifies our corporate structure, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us.

Our Term B Loan is secured by a lien on substantially all of our and the guarantors' personal property and material real property assets (if any). If we default under the terms of the Term B Loan, the lenders may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse effect as defined under the Term B Loan agreement. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Satisfying the obligations of this debt could adversely affect the amount or timing of any distributions to our stockholders. We may choose to satisfy, repurchase, or refinance this debt through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of the Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result in a default under the indenture, 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.

If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business may be impaired.

We have a small management team and very few employees. We are highly dependent on principal members of our management team and a small group of key employees to operate our business. None of our employees have employment commitments for any fixed period of time and all may leave our employment at will. If we fail to retain our qualified personnel or to replace them when they leave, our ability to manage our business may be impaired, which may cause the price of our securities to fall.

Table of Contents

We rely and will continue to rely on outsourcing arrangements for many of our activities, including financial reporting and accounting and human resources.

As of December 31, 2018, we had only six employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including financial reporting and accounting and human resources, as well as for certain of our functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

Our internal computer systems, or third-parties that we work with, may fail or suffer security breaches, which could result in a material disruption of our business.

Despite the implementation of security measures, our internal computer systems and those of third-parties with whom we work (including our collaborative partner) are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. In the event we or they were to experience any significant system failure, accident or security breach it could cause interruptions in our operations and adversely affect our business, financial condition and results of operations. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential, or otherwise protected, information and corruption of data.

If we fail to maintain proper and effective internal control over financial reporting or if the interpretations, estimates or judgments utilized in preparing our financial statements prove to be incorrect, our operating results and our ability to operate our business could be harmed.

The Sarbanes-Oxley Act requires, among other things, that we establish and maintain effective internal control over financial reporting and disclosure controls and procedures. Under the SEC's current rules, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our independent registered public accounting firm is also required to report on our internal control over financial reporting. Our testing and our independent registered public accounting firm's testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses and render our internal control over financial reporting ineffective. We have and expect to continue to incur substantial accounting and auditing expense and to expend significant management time in complying with the requirements of Section 404. If we are not able to maintain compliance with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to investigations or sanctions by the SEC, FINRA, The Nasdaq Global Select Market or other regulatory authorities. In addition, we could be required to expend significant management time and financial resources to correct any material weaknesses that may be identified or to respond to any regulatory investigations or proceedings.

We are also subject to complex tax laws, regulations, accounting principles and interpretations thereof. The preparation of our financial statements requires us to interpret accounting principles and guidance and make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our interpretations, estimates and judgments 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

Table of Contents

the preparation of our financial statements. U.S. generally accepted accounting principles ("GAAP") presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. In the event that one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results. The need to restate our financial results could, among other potential adverse effects, result in our incurring substantial costs, affect our ability to timely file our periodic reports until such restatement is completed, divert the attention of our management and employees from managing our business, result in material changes to our historical and future financial results, result in investors losing confidence in our operating results, subject us to securities class action litigation, and cause our stock price to decline.

As we continue to develop our business, our mix of assets and our sources of income may require that we register with the SEC as an "investment company" in accordance with the Investment Company Act of 1940.

We have not been and have no current intention to register as an "investment company" under the Investment Company Act of 1940 or the "40 Act", because we believe the nature of our assets and the sources of our income currently exclude us from the definition of an investment company pursuant to Sections (3)(a)(1)(A), (3)(a)(1)(C) under the 40 Act and Rule 270.3a-1 of Title 17 of the Code of Federal Regulations. Accordingly, we are not currently subject to the provisions of the 40 Act, such as compliance with the 40 Act's registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. Generally, to avoid being a company that is an "investment company" under the 40 Act, it must both (a) not be or hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, and (b) either (i) not be engaged or propose to engage in the business of investing in securities or own or propose to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis or (ii) not have more than 45% of the value of its total assets (exclusive of government securities and cash items) consist of or more than 45% of its net income after taxes (for the last four fiscal quarters combined) be derived from securities. In addition, we would not be an "investment company" if an exception, exemption, or safe harbor under the 40 Act applies.

We monitor our assets and income for compliance with the tests under the 40 Act and seek to conduct our business activities to ensure that we do not fall within its definitions of "investment company." If we were to become an "investment company" and be subject to the strictures of the 40 Act, the restrictions imposed by the 40 Act would likely require changes in the way we do business and add significant administrative burdens to our operations. In order to ensure that we do not fall within the 40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include restructuring the Company and/or modifying our mixture of assets and income.

Specifically, our mixture of debt versus royalty assets is important to our classification as an "investment company" or not. In this regard, while we currently believe that none of the definitions of "investment company" apply to us, we may in the future rely on an exception under the 40 Act provided by Section 3(c)(5)(A). To qualify for Section 3(c)(5)(A), as interpreted by the staff of the SEC, we would be required to have at least 55% of our total assets in "notes, drafts, acceptances, open accounts receivable, and other obligations representing part or all of the sales price of merchandise, insurance, and services" (or "Qualifying Assets"). In a no-action letter issued to Royalty Pharma on August 13, 2010, the SEC staff stated that royalty interests are Qualifying Assets under this exception. If the SEC or its staff in the future adopts a contrary interpretation or otherwise restricts the

Table of Contents

conclusions in the staff's no-action letter such that our royalty interests are no longer Qualifying Assets for purposes of Section 3(c)(5)(A), we could be required to register under the 40 Act.

The rules and interpretations of the SEC and the courts, relating to the definition of "investment company" are highly complex in numerous respects. While we currently intend to conduct our operations so that we will not be deemed an investment company, we can give no assurances that we will not determine it to be in the Company's and our stockholders' interest to register as an "investment company," not be deemed an "investment company" and not be required to register under the 40 Act.

Prolonged economic uncertainties or downturns, as well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business.

The global economic downturn and market instability has made the business climate more volatile and more costly. These economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control and may make any necessary debt or equity financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a lingering economic downturn or significant increase in our expenses could require additional financing at less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our stock price and could require us to delay or abandon clinical development plans.

Sales of our partnered products will be dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of negative trends in the general economy in the U.S. or other jurisdictions in which we may do business, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our or our partners' product sales and revenue.

In addition, we rely on third parties for several important aspects of our business. During challenging and uncertain economic times and in tight credit markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or partners. If such third parties are unable to satisfy their commitments to us, our business and results of operations would be adversely affected.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with applicable regulations, provide accurate information to regulatory authorities, comply with federal and state fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, the health care industry is subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Table of Contents

We have incurred litigation and may incur additional litigation.

We have been subject to various legal proceedings, and, in the future, we may be exposed to, or threatened with, litigation, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. In addition, agreements entered into by us sometimes include indemnification provisions which may subject us to costs and damages in the event of a claim against an indemnified third party.

Regardless of the merit of particular claims, litigation may be expensive, time-consuming, disruptive to our operations and distracting to management. In recognition of these considerations, we may enter into agreements or other arrangements to settle litigation and resolve such disputes. No assurance can be given that such agreements can be obtained on acceptable terms or that litigation will not occur. These agreements may also significantly increase our operating expenses.

If one or more legal matters were resolved against us or an indemnified third party in a reporting period for amounts in excess of management's expectations, our consolidated financial statements for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against us that could materially adversely affect our financial condition and operating results.

While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise.

Risks Related to our Alliance with GSK

Because all our current and projected revenues are derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.

All of our current and projected revenues are derived from products under the GSK Agreements. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In addition, while we obtained GSK's consent to the Spin-Off as structured, GSK could decide to challenge various aspects of our post-Spin-Off operation of TRC, the limited liability company jointly owned by us and Theravance Biopharma, as violating or allowing it to terminate the GSK Agreements. Although we believe our operation of TRC fully complies with the GSK Agreements and applicable law, there can be no assurance that we would 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 market or investor uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and in other material harm to our business.

Because GSK is a strategic partner as well as a significant stockholder, it may take actions that in certain cases are materially harmful to our business or to our other stockholders.

Although GSK beneficially owns approximately 31.7% of our outstanding common stock as of December 31, 2018, it is also a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from our interests and those of our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements

Table of Contents

about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its non-GSK/Innoviva respiratory products or a partnered product for which we are entitled to receive a lower percentage of royalties, delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements, or take other actions, such as making public statements, that have a negative effect on our stock price. In this regard and by way of example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®. Also, given the potential future royalty payments which GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us in order to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in our best interest or the best interest of our other stockholders. In addition, following the FDA regulatory approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements has had the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following this regulatory approval have been guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the products covered by the GSK Agreements in the future. In addition, following the expiration of our governance agreement with GSK in September 2015, GSK is no longer subject to the restrictions thereunder regarding the voting of the shares of our common stock owned by it.

GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements have had the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements, which may be harmful to both our business and our stockholders.

Following the FDA approval of TRELEGY® ELLIPTA® in September 2017, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements have had the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. As such, GSK may prioritize TRELEGY® ELLIPTA®, and if GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, this may be harmful to our business, operations and stock price. If GSK prioritizes TRELEGY® ELLIPTA®, we will only be entitled to a 15% economic interest of the royalties paid pursuant to the commercialization of our partnered products or chooses to reprioritize its commercial programs, our businesses, operations and stock price would be negatively affected.

GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions.

In the course of our discussions with GSK concerning the Spin-Off of Theravance Biopharma, GSK indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under the GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK's consent, a third party in a

Table of Contents

proposed monetization transaction may nonetheless insist that we obtain GSK's consent for the transaction or restructure the transaction on less favorable terms. We have obtained GSK's agreement that (i) we may grant certain pre-agreed covenants in connection with monetization of our interests in RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy and portions of our interests in TRC, and (ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided among other conditions, that in each case, the covenants are not granted in favor of a pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK's consent to grant covenants other than pre-agreed covenants, we may not be able to obtain GSK's consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by the GSK Agreement without GSK's consent, GSK could request that its consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK Agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in defending against GSK's claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK Agreements or the loss of potential royalties from the respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.

GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.

As of December 31, 2018, GSK beneficially owned approximately 31.7% of our outstanding common stock. As such, GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business. The procedures previously governing and restricting GSK offers to our stockholders to acquire outstanding voting stock and the restrictions regarding the voting of shares of our common stock owned by it terminated upon the expiration of the governance agreement in September 2015. Further, pursuant to our Certificate of Incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

GSK's significant ownership position may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As of December 31, 2018, GSK beneficially owned approximately 31.7% of our outstanding common stock. As a result of GSK's significant ownership, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

GSK could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

GSK is not subject to any contractual restrictions with us on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers

Table of Contents

were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by GSK of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

Risks Related to Legal and Regulatory Uncertainty

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which are necessary to build name and brand recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trademarks or trade names similar to ours, thereby impeding our ability to build name and brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. There is also a risk that if there is confusion in the marketplace, the reputation, performance and/or actions of such third parties may negatively impact our stock price and our business. We therefore adopted a new brand, Innoviva, in January 2016. Over the long term, if we are unable to establish name and brand recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If we fail to promote and maintain our brand successfully, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our business may be harmed.

Failure to comply with the U.S. Foreign Corrupt Practices Act, or "FCPA", as well as the anti-bribery laws of the nations in which we conduct business, could subject us to penalties and other adverse consequences.

We are subject to the FCPA, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls. In addition, we are subject to the anti-bribery laws of other jurisdictions in which we conduct business. Our employees or other agents may engage in prohibited conduct without our knowledge under our policies and procedures and the FCPA and other anti-bribery laws that we may be subject to for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to products in any respiratory program partnered with GSK are not adequate, the future commercialization of any such product could be delayed, limited or prevented, which would materially harm our business and the price of our securities could fall.

To the extent the intellectual property protection of products in any respiratory program partnered with GSK are successfully challenged or encounter problems with the U.S. Patent and Trademark Office or other comparable agencies throughout the world, the commercialization of these products could be delayed, limited or prevented. Any challenge to the intellectual property protection of a late-stage development asset or approved product arising from any respiratory program partnered with GSK could harm our business and cause the price of our securities to fall.

Our commercial success depends in part on products in any respiratory program partnered with GSK not infringing the patents and proprietary rights of third parties. Third parties may assert that these products are using their proprietary rights without authorization. In addition, third parties may

Table of Contents

obtain patents in the future and claim that use of GSK's technologies infringes upon these patents. Furthermore, parties making claims against GSK may obtain injunctive or other equitable relief, which could effectively block GSK's ability to further develop or commercialize one or more of the product candidates or products in any respiratory program partnered with GSK.

In the event of a successful claim of infringement against GSK, it 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, GSK may need to obtain licenses from third parties to advance its research or allow commercialization of the products. GSK may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, GSK would be unable to further develop and commercialize one or more of the products, which could harm our business significantly. In addition, in the future GSK could be required to initiate litigation to enforce its proprietary rights against infringement by third parties. Prosecution of these claims to enforce its rights against others would involve substantial litigation expenses. If GSK fails to effectively enforce its proprietary rights related to our partnered respiratory programs against others, our business will be harmed, and the price of our securities could fall.

Risks Related to Ownership of our Common Stock

The price of our securities has been volatile and may continue to be so, and purchasers of our securities could incur substantial losses.

The price of our securities has been volatile and may continue to be so. Between January 1, 2018 and December 31, 2018, the high and low sales prices of our common stock as reported on The Nasdaq Global Select Market varied between $13.26 and $18.60 per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

- any adverse developments or results or perceived adverse developments or results with respect to the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of pricing pressure in the respiratory markets targeted by our partnered products or existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;

- any positive developments or results or perceived positive developments or results with respect to the commercialization of TRELEGY® ELLIPTA® with GSK, including, if GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®;

- any adverse developments or results or perceived adverse developments or results with respect to the ongoing development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious or does not sufficiently differentiate itself from alternative therapies;

- any adverse developments or results or perceived adverse developments or results with respect to the on-going development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, or any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;

Table of Contents

any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA (or comparable foreign regulatory authority) policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);

GSK reprioritizing its development or commercial efforts on other products, including TRELEGY® ELLIPTA® or products owned by GSK (such as Advair®) but that are not partnered with us;

the occurrence of a fundamental change triggering a put right of the holders of the Notes or our inability, or perceived inability, to satisfy the obligations under the Notes when they become due;

our incurrence of expenses in any particular quarter that are different than market expectations;

changes in the treatment paradigm or standards of care for COPD or asthma;

the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI and TRELEGY® ELLIPTA®, through commercialization in all indications in all major markets;

any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;

decisions by GSK with respect to the MABA program;

announcements by or regarding GSK generally;

announcements of patent issuances or denials, technological innovations or new commercial products by GSK;

publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by GSK;

regulatory developments in the U.S. and foreign countries, including recent tax reform and the possibility that the current presidential administration and the U.S. Congress may replace PPACA and related legislation with new healthcare legislation;

economic and other external factors beyond our control;

sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended;

relative illiquidity in the public market for our common stock (our four largest stockholders other than GSK collectively owned approximately 26.9% of our outstanding common stock as of December 31, 2018 based on our review of publicly available filings); and

potential sales or purchases of our common stock by GSK.

We may be unable to or elect not to continue returning capital to our stockholders.

In recent years, we have focused on returning capital to stockholders and paid quarterly dividends during the third and fourth quarters of 2014 and during the first three quarters of 2015. From October 2015 through December 31, 2017, we repurchased an aggregate of 17,307,790 shares of our common stock for a total of $201.2 million. The payment of, or continuation of, capital returns to stockholders is at the discretion of our Board of Directors and is dependent upon our financial condition, results of

Table of Contents

operations, capital requirements, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our Board of Directors. Future capital returns may also be affected by, among other factors: our views on potential future capital requirements for investments in acquisitions and our working capital and debt maintenance requirements; legal risks; stock or debt repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital return programs may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. Our announcement of future capital return programs does not obligate us to repurchase any specific dollar amount of debt or equity or number of shares of common stock. A reduction, suspension or change in our capital return programs could have a negative effect on our stock price.

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

As of December 31, 2018, GSK beneficially owned approximately 31.7% of our outstanding common stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 4.6% of our outstanding common stock. Based on our review of publicly available filings as of December 31, 2018, our three largest stockholders other than GSK and investors affiliated with our executive officers and directors collectively owned approximately 22.4% of our outstanding common stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares. Following the expiration of the governance agreement in September 2015, GSK is no longer subject to the restrictions thereunder regarding the voting of the shares of our common stock owned by it.

Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay a change in control of our company.

Provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our Certificate of Incorporation and Bylaws;
- restricting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at meetings.

In addition, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters consist of a lease of 8,427 square feet of office space in Brisbane, California, which expires in June 2023. We have initiated the process of optimizing our headquarters space, which could include subleasing. We do not own or lease any other properties.

Table of Contents

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock was traded on Nasdaq under the symbol "THRX" from October 5, 2004 until January 8, 2016. Upon changing our corporate name to Innoviva, Inc. on January 7, 2016, we changed the stock ticker symbol to "INVA" effective January 11, 2016.

Holders

As of February 11, 2019, there were 79 stockholders of record of our common stock. As many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Purchases of Equity Securities by the Issuer

There were no purchases made by the Company of its own equity securities for the year ended December 31, 2018.

Stock Performance Graph

The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on December 31, 2013 and ending on December 31, 2018, with the cumulative total return of (i) the Nasdaq Composite Index, (ii) the Nasdaq S&P Small Cap 600 Pharma Index and (iii) the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100.00 on December 31, 2013 in each of (1) our common stock, (2) the Nasdaq Composite Index, (3) the Nasdaq S&P Small Cap 600 Pharma Index and (4) the Nasdaq Biotechnology Index, and assumes the reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from sources believed to be reliable including Nasdaq, Bloomberg and Reuters, but we are not responsible for any errors or omissions in such information.

Notwithstanding anything to the contrary set forth in any of our previous or future filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate this Annual Report on Form 10-K or future filings made by us under those statutes, this Stock 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.

Table of Contents

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Innoviva, Inc. the Nasdaq Composite Index, Nasdaq Biotechnology Index, and Nasdaq S&P Small Cap 600 Pharma Index

---

* $100 invested on December 31, 2013 in stock or index, including reinvestment of dividends. The performance chart for Innoviva is adjusted for the June 2014 Spin-Off, in which each of our stockholders received one ordinary share of Theravance Biopharma, Inc. for every 3.5 shares of our common stock.

ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated summary financial data below should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II, Item 8, "Financial Statements and Supplementary Data," in this Annual

Table of Contents

Report on Form 10-K. The historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except per share data)				
CONSOLIDATED STATEMENTS OF OPERATIONS DATA					
Net revenue	$ 261,004	$ 217,217	$ 133,569	$ 53,949	$ 8,433
Total operating expenses	22,753	33,613	24,581	22,369	42,362
Income (loss) from operations	238,251	183,604	108,988	31,580	(33,929)
Interest and other income (expense), net	(4,042)	(5,727)	3,059	1,443	(2,711)
Interest expense	(23,954)	(43,601)	(52,416)	(51,803)	(36,892)
Income (loss) from continuing operations before income taxes	210,255	134,276	59,631	(18,780)	(73,532)
Income tax benefit (expense), net[1]	196,073	(4)	(95)	20	2
Net income from continuing operations	406,328	134,272	59,536	(18,760)	(73,530)
Loss from discontinued operations[2]					(94,934)
Net income (loss)	406,328	134,272	59,536	(18,760)	(168,464)
Net income attributable to noncontrolling interest	11,272	129			
Net income (loss) attributable to Innoviva stockholders	$ 395,056	$ 134,143	$ 59,536	$ (18,760)	$ (168,464)
Basic net income (loss) per share attributable to Innoviva stockholders					
Continuing operations	$ 3.92	$ 1.25	$ 0.54	$ (0.16)	$ (0.66)
Discontinued operations					(0.84)
Basic net income (loss) per share	$ 3.92	$ 1.25	$ 0.54	$ (0.16)	$ (1.50)
Diluted net income (loss) per share attributable to Innoviva stockholders:					
Continuing operations	$ 3.53	$ 1.17	$ 0.53	$ (0.16)	$ (0.66)
Discontinued operations					(0.84)
Diluted net income (loss) per share	$ 3.53	$ 1.17	$ 0.53	$ (0.16)	$ (1.50)
Shares used to compute basic net income (loss) per share attributable to Innoviva stockholders	100,849	106,945	110,280	115,372	112,059
Shares used to compute diluted net income (loss) per share attributable to Innoviva stockholders	113,408	119,866	123,233	115,372	112,059
Cash dividends declared per common share	$	$	$	$ 0.75	$ 0.50

	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				

CONSOLIDATED BALANCE SHEETS DATA					
Cash, cash equivalents and marketable securities	$ 114,908	$ 129,075	$ 150,433	$ 187,283	$ 283,354
Working capital	193,343	165,627	177,997	200,834	238,426
Total assets	548,193	367,337	378,996	408,932	521,654
Long-term liabilities	383,441	575,302	711,938	738,086	731,247
Accumulated deficit	(1,103,692)	(1,498,748)	(1,632,891)	(1,692,427)	(1,673,667)
Total Innoviva stockholders' equity (deficit)	153,583	(242,859)	(352,991)	(342,645)	(223,349)

(1) In the year ended December 31, 2018, we recorded an income tax benefit of $196.1 million primarily due to the release of a valuation allowance on our deferred tax assets.

Table of Contents

(2) On June 1, 2014, we spun off our research and drug development operations to Theravance Biopharma. The results of operations for the former research and drug development operations until June 1, 2014 are included above as part of discontinued operations.

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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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

Innoviva, Inc. ("Innoviva", the "Company", the "Registrant" or "we" and other similar pronouns) is focused on royalty management. Innoviva's portfolio includes the respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI"), ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "UMEC/VI") and TRELEGY® ELLIPTA® (the combination FF/UMEC/VI). Under the Long-Acting Beta2 Agonist ("LABA") Collaboration Agreement, Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion; and royalties from the sales of ANORO® ELLIPTA® which tier upward at a range from 6.5% to 10%. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), including TRELEGY® ELLIPTA® and any other product or combination of products that may be discovered or developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

Our company structure and organization are tailored to our focused activities of managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, and providing for certain essential reporting and management functions of a public company. As of December 31, 2018, we had six employees. Our revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

Financial Highlights

In the year ended December 31, 2018, the net income attributable to Innoviva stockholders was $395.1 million, an improvement of $261.0 million from net income of $134.1 million in the year ended December 31, 2017, primarily due to an income tax benefit of $196.1 million, an increase in net royalty revenue, reduction in operating expenses and a decrease in interest expense. Cash, cash equivalents, and marketable securities totaled $114.9 million as of December 31, 2018, a decrease of $14.2 million

Table of Contents

from December 31, 2017. The decrease was primarily due to the principal repayments of $230.0 million on our Term B Loan. These outflows were partially offset by cash provided by operating activities of $223.5 million.

Collaborative Arrangements with GSK

LABA Collaboration

In November 2002, we entered into LABA collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma (the "LABA Collaboration Agreement"). For the treatment of COPD, the collaboration has developed three combination products:

RELVAR®/BREO® ELLIPTA® ("FF/VI") (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid ("ICS"), fluticasone furoate ("FF"),

ANORO® ELLIPTA® ("UMEC/VI"), a once-daily medicine combining a long-acting muscarinic antagonist ("LAMA"), umeclidinium bromide ("UMEC"), with a LABA, VI, and

TRELEGY® ELLIPTA® (the combination FF/UMEC/VI), a once-daily combination medicine consisting of an ICS, LAMA and LABA.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, in accordance with the LABA Collaboration Agreement, we paid milestone fees to GSK totaling $220.0 million during the year ended December 31, 2014. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing commercialization activities under the LABA Collaboration Agreement, including participation in the joint steering committee and joint project committee that are expected to continue over the life of the agreement. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the products.

We are entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion. For other products combined with a LABA from the LABA collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.

We are also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to TRC in connection with the Spin-off including TRELEGY® ELLIPTA®, which royalties are upward tiering and range from 6.5% to 10%.

2004 Strategic Alliance

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Innoviva-discovered preclinical MABA compounds (the "Additional MABAs"). The development program was funded in full by GSK. GSK is in the process of determining the next steps for the program. As a result of the transactions effected by the Spin-Off, we are only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of products that may be developed under the Strategic Alliance Agreement, such as MABA, and MABA/FF, while Theravance Biopharma receives 85% of those same payments.

Table of Contents

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. 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 as of the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. 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.

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 will 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. Through September 30, 2018, we maintained a full valuation allowance on our deferred tax assets.

In the fourth quarter of 2018, we recorded an income tax benefit of approximately $196.1 million related to the reversal of a valuation allowance on our deferred tax assets. This non-cash income tax benefit is non-recurring and relates primarily to $0.8 billion of U.S. federal net operating losses, and certain federal R&D credits which are expected to be utilized in the future. We expect to recognize income tax expense in 2019 and future periods, primarily based on the 21% federal tax rate, but we do not expect to use cash to pay U.S. federal or California income taxes until after we utilize the available deferred tax assets.

The valuation allowance was released on the majority of our deferred tax assets based on our assessment of our historical trend of taxable income in recent years and our projection of future taxable income. The recognition and measurement of income tax benefits requires significant judgment. Our judgment might change as new information becomes available. We will continue to evaluate our deferred tax assets each reporting period to determine whether adjustments to our valuation allowance are required. Deferred tax assets will be recognized based on the consideration of all available positive and negative evidence, including the differences between our anticipated and actual future operating results, using a "more likely than not" standard.

Revenue Recognition

In May 2014, the FASB issued a new comprehensive revenue recognition standard, ASC 606. We adopted this standard on January 1, 2018 on a modified retrospective basis. Under the new guidance, revenue is recognized when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue is recognized through a five-step process: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price for the contract; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) a performance obligation is satisfied.

The adoption of ASC 606 did not have a material impact on our consolidated financial statements as we do not have any unrecognized transaction price, other than sales-based royalty revenue, or any

Table of Contents

remaining performance obligations under our collaboration agreements. We continue to recognize the royalty revenue on licensee net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned and reported to us. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Under the GSK Agreements, we recognized net revenue of $261.0 million, $217.2 million and $133.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Capitalized Fees paid to a Related Party

We capitalize fees paid to licensors related to agreements for approved products or commercialized products ("Capitalized Fees"). Our gross Capitalized Fees of $220.0 million as of December 31, 2018 consist of registrational and launch-related milestone fees paid to GSK. We capitalized these fees as capitalized fees paid to a related party and amortize these Capitalized Fees on a straight-line basis over their estimated useful lives upon the commercial launch of the products. The estimated useful lives of these Capitalized Fees are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these Capitalized Fees is recognized as a reduction of royalty revenue. Amortization expense for each of the years ended December 31, 2018, 2017 and 2016 was $13.8 million. The remaining estimated amortization expense is $13.8 million for each of the years from 2019 to 2023 and $83.9 million thereafter.

We review our Capitalized Fees for impairment on a product-by-product basis for each major geographic area when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of Capitalized Fees is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. The determination of recoverability typically requires various estimates and assumptions, including estimating the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We derive the required cash flow estimates from near-term forecasted product sales and long-term projected sales in the corresponding market. Based upon our analyses, no impairment charges have been recorded on the Capitalized Fees as of December 31, 2018.

Fair Value of Stock-Based Compensation Awards

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options as of the date of grant. The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. We use the "simplified" method as described in Staff Accounting Bulletin No. 107, "Share Based Payment," for the expected option term. We use our historical volatility to estimate expected stock price volatility. The estimated fair value of the option is expensed on a ratable basis over the expected term of the grant.

We determine the fair value of RSUs and RSAs based on the fair market values of the underlying stock on the dates of grant. The fair value of service based RSUs and RSAs is expensed on a ratable or straight-line basis over the expected term of the vesting. The fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. We assess the probability of the performance indicators being met on a continuous basis. The grant date fair value of the RSUs and RSAs with a market condition is determined using a Monte Carlo valuation model and the compensation expense is recognized over the implied service period.

Table of Contents

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures as of the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The estimated annual forfeiture rates for stock options, RSUs and RSAs are based on our historical forfeiture experience.

For more information, refer to Note 6, "Stock-Based Compensation," to the consolidated financial statements appearing in this Annual Report on Form 10-K.

Accounting for Convertible Senior Notes Due 2025

On August 7, 2017, we completed a private placement of $192.5 million aggregate principal amount of our 2025 Notes. Due to our ability to settle the conversion obligation of the 2025 Notes in cash, common stock or a combination of cash and common stock, at our option, we separately account for the liability and equity components of the 2025 Notes by allocating the proceeds between the liability component and the embedded conversion option ("equity component"). The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature using the income approach. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2025 Notes of $67.3 million was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2025 Notes and the fair value of the liability of the 2025 Notes on the date of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Results of Operations

Net Revenue

Total net revenue, as compared to the prior years, was as follows:

				Change			
	Year Ended December 31,			2018		2017	
(In thousands)	2018	2017	2016	$	%	$	%
Royalties from a related party RELVAR/BREO	$ 220,162	$ 198,726	$ 128,638	$ 21,436	11%	$ 70,088	54%
Royalties from a related party ANORO	41,286	29,036	17,869	12,250	42	11,167	62
Royalties from a related party TRELEGY	13,379	179		13,200	*	179	*
Total royalties from a related party	274,827	227,941	146,507	46,886	21	81,434	56
Less: amortization of capitalized fees paid to a related party	(13,823)	(13,823)	(13,823)				
Royalty revenue	261,004	214,118	132,684	46,886	22	81,434	61
Strategic alliance MABA program license		3,099	885	(3,099)	*	2,214	250
Total net revenue from GSK	$ 261,004	$ 217,217	$ 133,569	$ 43,787	20%	$ 83,648	63%

* Not Meaningful

Total net revenue increased for the year ended December 31, 2018, compared to the year ended December 31, 2017 and the year ended December 31, 2016, primarily due to continuing growth in

Table of Contents

prescriptions and market share for both RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, and initiation of sales by GSK of TRELEGY® ELLIPTA® in the fourth quarter of 2017. In the fourth quarter of 2017, due to the completion of Innoviva's performance obligations under the MABA program, we revised the performance period, which was previously estimated to end in June 2020. The change in this estimate resulted in full recognition of the remaining deferred revenue balance.

The revenue growth during the years ended December 31, 2018 and 2017 may not be indicative of our future revenue growth, if any.

Research & Development

Research & Development ("R&D") expenses, as compared to the prior years, were as follows:

				Change			
	Year Ended December 31,			2018		2017	
(In thousands)	2018	2017	2016	$	%	$	%
Research and development expenses	$	$ 1,355	$ 1,393	$ (1,355)	*	$ (38)	(3)%

*

Not Meaningful

We did not incur R&D expenses during the year ended December 31, 2018.

R&D expenses for the years ended December 31, 2017 and 2016 related to the late-stage partnered respiratory assets with GSK.

General & Administrative

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

				Change			
	Year Ended December 31,			2018		2017	
(In thousands)	2018	2017	2016	$	%	$	%
General and administrative expenses	$ 20,053	$ 32,258	$ 23,188	$ (12,205)	(38)%	$ 9,070	39%
General and administrative expenses-related party	2,700			2,700			

General and administrative expenses for the year ended December 31, 2018 were $20.1 million compared with $32.3 million in the year ended December 31, 2017, a decrease of $12.2 million. The amount for the year ended December 31, 2017 included $8.1 million of net proxy contest and associated litigation costs. General and administrative expenses for the year ended December 31, 2018 included $5.7 million cash severance costs in connection with certain members of senior management's separation from the Company and payment of $2.7 million to Sarissa pursuant to a settlement agreement in February 2018. The rest of the decrease in general and administrative expenses in the year ended December 31, 2018 is mainly attributable to lower personnel-related expenses, including net reversal of stock-based compensation expenses, as a result of lower headcount.

General and administrative expenses increased in the year ended December 31, 2017 compared to the year ended December 31, 2016 primarily due to net proxy contest and associated litigation costs of $8.1 million.

Table of Contents

Other Income (Expense), net and Interest Income

Other income (expense), net and interest income, as compared to the prior years, were as follows:

				Change			
	Year Ended December 31,			2017		2016	
(In thousands)	2018	2017	2016	$	%	$	%
Other income (expense), net	$ (5,702)	$ (7,038)	$ 2,477	$ 1,336	*	$ (9,515)	*
Interest income	1,660	1,311	582	349	27%	729	125%

*
Not Meaningful

Other expense, net for the year ended December 31, 2018, mainly consists of the loss on the extinguishment of debt of $5.7 million in relation to the prepayments of our Term B Loan. Other expense, net for the year ended December 31, 2017, primarily pertains to the loss on the extinguishment of debt of $7.3 million in relation to our redemptions of non-recourse notes due 2029 (the "2029 Notes"). Other income, net for the year ended December 31, 2016 primarily pertains to a realized gain of $2.3 million from the repurchases of our 2023 Notes during the year ended December 31, 2016.

Interest income increased in the year ended December 31, 2018 compared to the year ended December 31, 2017, and the year ended December 31, 2016, primarily due to higher interest generated from our investments in marketable securities.

Interest Expense

Interest expense, as compared to the prior years, was as follows:

				Change			
	Year Ended December 31,			2017		2016	
(In thousands)	2018	2017	2016	$	%	$	%
Interest expense	$ 23,954	$ 43,601	$ 52,416	$ (19,647)	(45)%	$ (8,815)	(17)%

Interest expense decreased for the year ended December 31, 2018, compared to the prior year primarily due to the lower average outstanding debt balance resulting from $230.0 million in prepayments on our Term B Loan in 2018.

Interest expense decreased in the year ended December 31, 2017 compared to the year ended December 31, 2016 primarily due to redemption of our 2029 Notes using the net proceeds from the Term B Loan and 2025 Notes, the lower interest rates starting August 2017 under the Term B Loan and 2025 Notes compared to the interest rates of the 2029 Notes, and lower principal balance resulting from repurchase of our 2023 Notes.

Income Taxes

Income tax benefit (expense), net, as compared to the prior years, was as follows:

				Change			
	Year Ended December 31,			2017		2016	
(In thousands)	2018	2017	2016	$	%	$	%
Income tax benefit (expense), net	$ 196,073	$ (4)	$ (95)	$ 196,077	*	$ 91	*

*
Not Meaningful

Table of Contents

As of December 31, 2018, 2017 and 2016, we had net operating loss carryforwards for federal income taxes of $0.8 billion, $1.0 billion and $1.1 billion, respectively. As of December 31, 2018, 2017 and 2016, we had federal research and development tax credit carryforwards of $44.8 million, $45.2 million, and $45.2 million, respectively.

For the year ended December 31, 2018, we evaluated whether it was more likely than not that some portion or all deferred tax assets will be realized in the future based on all available positive and negative evidence, including but not limited to our historical operating results and our expectation of future profitability, and concluded that we will be able to realize approximately $190.2 million and $5.9 million benefits of the U.S. federal and state deferred tax assets in the future, respectively. Accordingly, we released our valuation allowance on these deferred tax assets as of December 31, 2018. See Note 9, Income Taxes in our audited financial statements for additional information. For the years ended December 31, 2017 and 2016, we recorded a valuation allowance to offset in full the benefit related to our deferred tax assets because realization of these benefits was uncertain.

We had unrecognized tax benefits of $15.4 million as of December 31, 2018. Total unrecognized tax benefits that, if recognized, would affect our effective tax rate, were $8.0 million as of December 31, 2018. Our total unrecognized tax benefits as of December 31, 2017 and 2016 were $15.5 million.

Utilization of net operating loss and tax credit carryforwards is subject to rules, provided by the Internal Revenue Code and similar state provisions, governing annual limitations tied to ownership changes. In addition, as a result of the passage of the Tax Cuts and Jobs Act, corporate tax rates in the United States decreased in 2018, which resulted in the remeasurement of our deferred tax assets at the new statutory rate and a reduction in the value of our deferred tax assets in 2017. We conducted an analysis through September 30, 2018 to determine whether an ownership change had occurred since inception. The analysis indicated that two ownership changes occurred in prior years. However, notwithstanding the applicable annual limitations, we estimate that no portion of the net operating loss or credit carryforwards will expire before becoming available to reduce federal and state income tax liabilities. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

Net Income Attributable to Noncontrolling Interest

Net income attributable to noncontrolling interest, as compared to the prior years, was as follows:

				Change			
	Year Ended December 31,			2017		2016	
(In thousands)	**2018**	**2017**	**2016**	**$**	**%**	**$**	**%**
Net income attributable to noncontrolling interest	$ 11,272	$ 129	$	$ 11,143	*	$ 129	*

* Not Meaningful

This represents the 85% share of net income in Theravance Respiratory Company, LLC for Theravance Biopharma for the years ended December 31, 2018 and 2017. The increase was primarily due to the increase in the growth in prescriptions and market share for TRELEGY® ELLIPTA®.

Liquidity and Capital Resources

Liquidity

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under collaborative arrangements. For the year ended December 31, 2018, we generated gross royalty revenues from GSK of

Table of Contents

$274.8 million. Net cash and cash equivalents, short-term investments and marketable securities totaled $114.9 million, and royalties receivable from GSK totaled $83.3 million, as of December 31, 2018.

On August 7, 2017, we completed a private placement of $192.5 million aggregate principal amount of our 2025 Notes. The proceeds include the 2025 Notes sold pursuant to the $17.5 million over-allotment option granted by us to the initial purchasers, which option was exercised in full. The 2025 Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"). The 2025 Notes will mature on August 15, 2025, unless repurchased or converted in accordance with their terms prior to such date. Concurrently with the pricing of the offering, we repurchased and retired 1,317,771 shares of our common stock for approximately $17.5 million of the net proceeds from the offering, in privately negotiated transactions effected through one of the initial purchasers or its affiliate, as our agent. The remaining net proceeds from the sale of the 2025 Notes in the offering were used to redeem a portion of the principal outstanding under the 2029 Notes on August 15, 2017.

On August 18, 2017, we entered into a Credit Agreement and completed a financing of the $250.0 million Term B Loan, the proceeds of which were used to repay the remaining balance of the 2029 Notes. The Term B Loan will mature on August 18, 2022. Two and a half percent (2.5%) of the initial principal amount was originally due quarterly beginning December 31, 2017. The remaining outstanding balance is due at maturity. Prepayments, in whole or in part, can be made at any time without a penalty. The Credit Agreement also provides us the ability to request one or more additional tranches of term loans (or increase an existing term loan) at any time prior to maturity. In December 2017, February 2018 and August 2018, we repaid the principal balance of the Term B Loan by $6.3 million, $120.0 million and $110.0 million, respectively. The outstanding principal balance of the Term B Loan as of December 31, 2018 was $13.8 million.

Adequacy of Cash Resources to Meet Future Needs

We believe that cash from projected future royalty revenues and our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated debt service and operating needs for at least the next 12 months based upon current operating plans and financial forecasts. If our current operating plans and financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as currently planned. In addition, from time to time we may restructure or reduce our debt, including through tender offers, redemptions, amendments, repurchases or otherwise, all consistent with the terms of our debt agreements.

Cash Flows

Cash flows, as compared to the prior years, were as follows:

	Year Ended December 31,			Change	
(In thousands)	**2018**	**2017**	**2016**	**2017**	**2016**
Net cash provided by operating activities	$ 223,531	$ 141,749	$ 60,984	$ 81,782	$ 80,765
Net cash provided by (used in) investing activities	3,519	(23,236)	(4,580)	26,755	(18,656)
Net cash used in financing activities	(237,969)	(163,193)	(97,568)	(74,776)	(65,625)

Table of Contents

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2018 was $223.5 million, consisting primarily of our net income of $406.3 million, adjusted for non-cash items such as $196.1 million of deferred income taxes, $13.9 million of depreciation and amortization, $7.7 million amortization of debt discount and issuance costs, $5.7 million of loss on debt extinguishment and $3.2 million of stock-based compensation expense, partially offset by an increase in receivables from collaborative arrangements of $12.7 million.

Cash provided by operating activities for the year ended December 31, 2017 was $141.7 million, consisting primarily of our net income of $134.3 million, adjusted for non-cash items such as $14.0 million of depreciation and amortization, $9.8 million for stock-based compensation expense, $7.3 million of loss on debt extinguishment and $5.1 million amortization of debt discount and debt issuance costs, offset by changes in operating assets and liabilities, including an increase in receivables from collaborative arrangements of $23.7 million and a reduction in deferred revenue of $3.1 million.

Cash provided by operating activities for the year ended December 31, 2016 was $61.0 million, consisting primarily of our net income of $59.5 million, adjusted for non-cash items such as $14.0 million of depreciation and amortization and $8.3 million for stock-based compensation expense, offset by changes in operating assets and liabilities, including an increase in receivables from collaborative arrangements of $20.6 million.

Cash Flows from Investing Activities

Net cash flows from investing activities for the year ended December 31, 2018 of $3.5 million was primarily due to $75.4 million of proceeds received from maturities of marketable securities, partially offset by $71.9 million in purchases of marketable securities.

Net cash used in investing activities for the year ended December 31, 2017 of $23.2 million was primarily due to $67.6 million in purchases of marketable securities, partially offset by $44.4 million of proceeds received from the sale and maturities of marketable securities.

Net cash used in investing activities for the year ended December 31, 2016 of $4.6 million was primarily due to $95.7 million in purchases of marketable securities, partially offset by $91.4 million of proceeds received from the sale and maturities of marketable securities.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2018 of $238.0 million was primarily due to $230.0 million in prepayments on our Term B Loan, $6.0 million distributions to noncontrolling interest and $3.1 million payments for the repurchase of shares to satisfy tax withholding.

Net cash used in financing activities for the year ended December 31, 2017 of $163.2 million was primarily due to $487.2 million principal repayments of our 2029 Notes and $97.5 million repurchases of our common stock. These outflows were partially offset by the net proceeds of $242.6 million from the financing of our Term B Loan and the net proceeds of $187.1 million from issuance of our convertible senior notes due 2025.

Net cash used in financing activities for the year ended December 31, 2016 of $97.6 million was primarily due to $78.1 million repurchases of common stock, $11.6 million repurchases of our 2023 Notes, and $6.8 million repayments on principal of our 2029 Notes.

Table of Contents

Off-Balance Sheet Arrangements

In June 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma. However, if Theravance Biopharma were to default on its lease obligations, we would be held liable by the landlord and thus, we have in substance guaranteed the lease payments for these facilities. We would also be responsible for lease-related payments including utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. As of December 31, 2018, the total remaining lease payments for the duration of the lease, which runs through May 2020, were $9.3 million. The carrying value of this lease guarantee was $0.5 million as of December 31, 2018 and is reflected in other long-term liabilities in our consolidated balance sheet.

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters. As such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of December 31, 2018.

Contractual Obligations and Commercial Commitments

In the table below, we set forth our significant enforceable and legally binding obligations and future commitments as of December 31, 2018.

		Payment Due by Period			
(In thousands)	**Total**	**Less Than 1 Year**	**1 - 3 Years**	**3 - 5 Years**	**More Than 5 Years**
2023 Notes	$ 264,028	$ 5,121	$ 10,242	$ 248,665	$
2025 Notes	226,188	4,813	9,625	9,625	202,125
Term B Loan*	13,750			13,750	
Facility lease	1,889	403	844	642	
Total	$ 505,855	$ 10,337	$ 20,711	$ 272,682	$ 202,125

* The Term B Loan balances reflect the principal repayment obligations and do not include the interest payments as the loan bears interest at a varying rate of three-month LIBOR plus a 4.5% margin.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to interest rate risk related to our portfolio of investments in debt securities and the debt that we have issued. We account for our investments in debt securities at fair value, with unrealized gains or losses recorded as a component of other comprehensive income. We believe that our exposure to interest rate risk on our investment portfolio is not material as the average remaining maturity of our investment portfolio was three months as of December 31, 2018.

Our debt portfolio includes the senior secured term loans under the Term B Loan which bear interest at a variable rate based on LIBOR plus 4.5% or a certain alternate base rate plus 3.5%. We are exposed to market risks related to fluctuations in interest rates on these loans. As of December 31, 2018, the stated interest rate for the Term B Loan, based on LIBOR, was 7.15%. However, the outstanding principal balance of the Term B Loan has been significantly reduced from $243.8 million as of December 31, 2017 to $13.8 million as of December 31, 2018. An increase in the LIBOR of 50 basis

Table of Contents

points would not materially impact our annual interest expense based on the outstanding balance of $13.8 million as of December 31, 2018.

We account for our 2023 Notes and 2025 Notes on an amortized cost basis and our recognized value of the debt does not reflect changes in fair value. Also, because our 2023 Notes and 2025 Notes bear interest at a fixed rate, our cash flows are not subject to variability as a result of changes in interest rates. However, we do disclose the estimated fair value of our debt and we are exposed to changes in fair value that may occur as a result of interest rate fluctuations. As of December 31, 2018, based on available pricing information, the fair values of our 2023 Notes and 2025 Notes were estimated to be $258.9 million and $230.7 million, respectively. The 2023 Notes and 2025 Notes bear interest at a fixed rate of 2.125% and 2.5%, respectively. Information about the contractual maturities of our debt is disclosed in the table within the Contractual Obligations and Commercial Commitments section of Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Table of Contents

INNOVIVA, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 62,417	$ 73,336
Short-term marketable securities	52,491	55,739
Related party receivables from collaborative arrangements	83,286	70,540
Prepaid expenses and other current assets	849	754
Total current assets	199,043	200,369
Property and equipment, net	160	209
Capitalized fees paid to a related party, net	152,899	166,722
Deferred tax assets	196,054	
Other assets	37	37
Total assets	$ 548,193	$ 367,337
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 11	$ 601
Accrued personnel-related expenses	470	1,721
Accrued interest payable	4,264	5,920
Other accrued liabilities	955	1,500
Current portion of long-term debt		25,000
Total current liabilities	5,700	34,742
Long-term debt, net of current portion, discount and issuance costs	382,855	574,362
Other long-term liabilities	586	940
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock: $0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock: $0.01 par value, 200,000 shares authorized, 101,098 issued and outstanding as of December 31, 2018 and 102,046 shares issued as of December 31, 2017	1,011	1,019
Treasury stock: 150 shares as of December 31, 2017		(3,263)
Additional paid-in capital	1,256,267	1,258,151
Accumulated other comprehensive loss	(3)	(18)
Accumulated deficit	(1,103,692)	(1,498,748)
Total Innoviva stockholders' equity (deficit)	153,583	(242,859)
Noncontrolling interest	5,469	152
Total stockholders' equity (deficit)	159,052	(242,707)
Total liabilities and stockholders' equity (deficit)	$ 548,193	$ 367,337

See accompanying notes to consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Royalty revenue from a related party, net of amortization of capitalized fees paid to a related party of $13,823 in the years ended December 31, 2018, 2017, and 2016, respectively	$ 261,004	$ 214,118	$ 132,684
Revenue from collaborative arrangements from a related party		3,099	885
Total net revenue	261,004	217,217	133,569
Operating expenses:			
Research and development		1,355	1,393
General and administrative	20,053	32,258	23,188
General and administrative related party	2,700		
Total operating expenses	22,753	33,613	24,581
Income from operations	238,251	183,604	108,988
Other income (expense), net	(5,702)	(7,038)	2,477
Interest income	1,660	1,311	582
Interest expense	(23,954)	(43,601)	(52,416)
Income before income taxes	210,255	134,276	59,631
Income tax benefit (expense), net	196,073	(4)	(95)
Net income	406,328	134,272	59,536
Net income attributable to noncontrolling interest	11,272	129	
Net income attributable to Innoviva stockholders	$ 395,056	$ 134,143	$ 59,536
Basic net income per share attributable to Innoviva stockholders	$ 3.92	$ 1.25	$ 0.54
Diluted net income per share attributable to Innoviva stockholders	$ 3.53	$ 1.17	$ 0.53
Shares used to compute Innoviva basic and diluted net income per share:			
Shares used to compute basic net income per share	100,849	106,945	110,280
Shares used to compute diluted net income per share	113,408	119,866	123,233

See accompanying notes to consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Net income	$ 406,328	$ 134,272	$ 59,536
Unrealized income (loss) on marketable securities, net	15	(19)	3
Comprehensive income	406,343	134,253	59,539
Comprehensive income attributable to noncontrolling interest	11,272	129	
Comprehensive income attributable to Innoviva stockholders	$ 395,071	$ 134,124	$ 59,539

See accompanying notes to consolidated financial statements.

Table of Contents

INNOVIVA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Innoviva Stockholders' Equity (Deficit)								
	Common Stock			Accumulated Other Comprehensive		Treasury Stock			Total Stockholders'
	Shares	Amount	Additional Paid-In Capital	Income (loss)	Accumulated Deficit	Shares	Amount	Noncontrolling Interest	Equity (Deficit)
Balance as of December 31, 2015	114,933	$ 1,149	$ 1,351,898	$ (2)	$ (1,692,427)	(150)	$ (3,263)	$	$ (342,645)
Exercise of stock options, and issuance of common stock units and stock awards	853	8	(674)						(666)
Partial termination of capped call options associated with repurchases of convertible notes due 2023			578						578
Stock-based compensation			8,297						8,297
Repurchase of common stock	(7,201)	(72)	(78,022)						(78,094)
Net income					59,536				59,536
Other comprehensive income				3					3
Balance as of December 31, 2016	108,585	1,085	1,282,077	1	(1,632,891)	(150)	(3,263)		(352,991)
Contributions from noncontrolling interest								23	23
Exercise of stock options, and issuance of common stock units and stock awards	891	9	(1,702)						(1,693)
Stock-based compensation			9,833						9,833
Cash dividend forfeited			7						7
Repurchase of common stock	(7,430)	(75)	(97,425)						(97,500)
Equity component of Covertible Senior Notes due 2025, net of issuance costs			65,361						65,361
Net income					134,143			129	134,272
Other comprehensive loss				(19)					(19)
Balance as of December 31, 2017	102,046	1,019	1,258,151	(18)	(1,498,748)	(150)	(3,263)	152	(242,707)
Distributions to noncontrolling interest								(5,955)	(5,955)
Exercise of stock options, and issuance of common stock units and stock awards	(798)	(8)	(1,926)						(1,934)
Stock-based compensation			3,233						3,233
Cash dividend forfeited			72						72
Retirement of treasury stock	(150)		(3,263)			150	3,263		
Net income					395,056			11,272	406,328
Other comprehensive income				15					15
Balance as of December 31, 2018	101,098	$ 1,011	$ 1,256,267	$ (3)	$ (1,103,692)		$	$ 5,469	$ 159,052

See accompanying notes to consolidated financial statements.

Table of Contents

INNOVIVA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net income	$ 406,328	$ 134,272	$ 59,536
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred income taxes	(196,054)		
Depreciation and amortization	13,872	13,982	13,954
Stock-based compensation	3,233	9,833	8,297
Amortization of debt discount and issuance costs	7,748	5,116	2,847
Loss (gain) on extinguishment of debt	5,745	7,256	(2,342)
Amortization of discount on short-term investments	(256)	(105)	(9)
Amortization of lease guarantee	(325)	(325)	(190)
Interest added to the principal balance of non-recourse notes due 2029			855
Changes in operating assets and liabilities:			
Receivables from collaborative arrangements	(12,746)	(23,693)	(20,619)
Prepaid expenses and other current assets	(95)	12	48
Other assets			(19)
Accounts payable	(590)	473	(690)
Accrued personnel-related expenses and other accrued liabilities	(1,677)	(81)	276
Accrued interest payable	(1,656)	(1,908)	(83)
Other long-term liabilities	4	16	8
Deferred revenue		(3,099)	(885)
Net cash provided by operating activities	223,531	141,749	60,984
Cash flows from investing activities			
Maturities of marketable securities	75,375	44,387	88,422
Purchases of marketable securities	(71,856)	(67,623)	(95,719)
Sales of marketable securities			2,995
Purchases of property and equipment			(278)
Net cash provided by (used in) investing activities	3,519	(23,236)	(4,580)
Cash flows from financing activities			
Repurchase of shares to satisfy tax withholding	(3,073)	(2,128)	(1,079)
Payments of principal on senior secured term loans	(230,000)	(6,250)	
Payments of cash dividends to stockholders	(80)	(281)	(960)
Proceeds from issuances of common stock, net	1,139	435	385
Proceeds from issuance of convertible senior notes due 2025		192,500	
Proceeds from senior secured term loans		250,000	
Payments of debt issuance costs and debt discount		(12,803)	
Payments of principal on non-recourse notes due 2029		(487,189)	(6,828)
Repurchase of common stock		(97,500)	(78,094)
Repurchase of convertible subordinated notes due 2023			(11,570)
Proceeds from capped-call options			578
Contributions from (distributions to) noncontrolling interest	(5,955)	23	
Net cash used in financing activities	(237,969)	(163,193)	(97,568)
Net decrease in cash and cash equivalents	(10,919)	(44,680)	(41,164)

Cash and cash equivalents at beginning of period	73,336	118,016	159,180
Cash and cash equivalents at end of period	$ 62,417	$ 73,336	$ 118,016