

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

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

or
For the transition period from _____ to _____

Commission File No. 000-30319

INNOVIVA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3265960
(I.R.S. Employer
Identification No.)

1350 Old Bayshore Highway, Suite 400

Burlingame, CA

(Address of principal executive offices)

94010

(Zip Code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange On Which Registered
Common Stock \$0.01 Par Value	INVA	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 No

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

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

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

Indicate by check mark whether 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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of the registrant's Common Stock on The Nasdaq Global Select Market on June 30, 2020 was \$876,605,331. This calculation does not reflect a determination that persons are affiliates for any other purpose.

On February 12, 2020, there were 101,392,397 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 2021 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2020, are incorporated by reference into Part III of this Annual Report. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this Annual Report on Form 10-K.

INNOVIVA, INC.
2020 Form 10-K Annual Report

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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; substantial competition from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies; the strategies, plans and objectives of the Company (related to the Company's growth strategy and corporate development initiatives beyond the Company's existing portfolio); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; risks related to the Company's growth strategy; 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.

PART I

ITEM 1. BUSINESS

Overview

Innoviva, Inc. (“Innoviva”, the “Company”, the “Registrant” or “we” and other similar pronouns) is a company with a portfolio of royalties and other healthcare assets. Our royalty portfolio contains 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 1350 Old Bayshore Highway, Suite 400, Burlingame, CA 94010. 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 increasing stockholder value by, among other things, maximizing the potential value of our respiratory assets partnered with GSK, optimizing our operations and augmenting capital allocation. We continue to diversify our primary royalty management business through actively pursuing opportunistic acquisitions of promising companies and assets in the healthcare industry and enhancing the returns on our capital.

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 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 Bifunctional Muscarinic Antagonist-Beta2 Agonist ("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. As a result of the transactions effected by the spin-off of Theravance Biopharma in June 2014 (the "Spin-Off"), the Strategic Alliance Agreement was assigned to TRC, which is entitled to receive 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. In June of 2020, GSK terminated the MABA program and agreed to pay a \$10.0 million termination fee to TRC. This fee was recognized as revenue from collaborative arrangements with a related party on our consolidated statements of income for the year ended December 31, 2020.

Common Stock owned by GSK

As of February 12, 2021, GSK beneficially owned approximately 31.6% of our outstanding common stock.

Recent Highlights

- GSK Net Sales:
 - Fourth quarter 2020 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$372.8 million, up 5% from \$354.4 million in the fourth quarter of 2019, with \$141.0 million in net sales from the U.S. market and \$231.8 million from non-U.S. markets.
 - Fourth quarter 2020 net sales of ANORO[®] ELLIPTA[®] by GSK were \$200.9 million, up 10% from \$182.7 million in the fourth quarter of 2019, with \$119.4 million net sales from the U.S. market and \$81.5 million from non-U.S. markets.
 - Fourth quarter 2020 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$313.6 million, up 42% from \$221.4 million in the fourth quarter of 2019, with \$212.9 million in net sales from the U.S. market and \$100.7 million in net sales from non-U.S. markets.
- Capital Allocation:
 - During December 2020, the Company entered into a strategic partnership with Sarissa Capital Management LP ("Sarissa Capital") designed to accelerate the execution of our strategy and enhance returns on our capital. As a part of the agreement, Sarissa Capital provides Innoviva with a range of advisory services advancing our acquisition strategy. In addition, the Company's wholly owned subsidiary, Innoviva Strategic Partners LLC, became a limited partner of ISP Fund LP (the "Partnership") and made an initial contribution of \$300 million for the purposes of investing in "long-only" securities in the healthcare, pharmaceutical and biotechnology industries. The general partner of the Partnership is an affiliate of Sarissa Capital, which acts as the investment adviser to the Partnership.
 - In January 2021, the Company entered into an agreement with Armata Pharmaceuticals, Inc. ("Armata"), pursuant to which it will invest, subject to certain closing conditions, additional \$20.0 million in 6.2 million shares of Armata common stock and an equal number of warrants with \$3.25 strike price in two tranches. At the closing of the first tranche, Innoviva acquired approximately 1.9 million shares of Armata common stock and 1.9 million warrants for an aggregate purchase price of \$6.1 million. Upon closing of the second tranche, Innoviva expects to own approximately 60% of Armata's outstanding stock.

Manufacturing

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

Government Regulation

The development and commercialization of products and product candidates pursuant to the GSK Agreements, or by entities that we have invested in or acquired, 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. 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, the ability to market 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 depends in part on obtaining patent protection for products and product candidates within our portfolio, including the products partnered with GSK. Accordingly, patents and other proprietary rights are essential elements of our business.

Our Strategic Partnership with Sarissa Capital

Strategic Advisory Agreement

On December 11, 2020, we entered into a Strategic Advisory Agreement (the "Services Agreement") with Sarissa Capital Management LP ("Sarissa Capital"), pursuant to which Sarissa Capital provides a variety of strategic services to us in order to assist us in the development and execution of our acquisition strategy intended to diversify our assets and the potential sources of revenue. Sarissa Capital is considered to be a related party due to its investment in Innoviva and its representation on our Board of Directors.

Partnership Agreement

On December 11, 2020, Innoviva Strategic Partners LLC, our wholly owned subsidiary (“Strategic Partners”), entered into a subscription agreement and an Amended and Restated Limited Partnership Agreement (the “Partnership Agreement”) pursuant to which Strategic Partners became a limited partner of ISP Fund LP (the “Partnership”). The general partner of the Partnership is an affiliate of Sarissa Capital and, pursuant to an investment management agreement, Sarissa Capital acts as the investment adviser to the Partnership. Strategic Partners made a \$300 million initial contribution to the Partnership. The Partnership was formed for the purposes of investing in “long-only” securities in the healthcare, pharmaceutical and biotechnology industries.

Competition

We anticipate that RELVAR[®]/BREQ[®] ELLIPTA[®] (FF/VI), ANORO[®] ELLIPTA[®] (UMEC/VI) and TRELEGY[®] ELLIPTA[®] (the combination FF/UMEC/VI) will compete with a number of approved bronchodilator drugs alone or in combination, 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 Resplick[®] (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) (Innoviva is 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 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 as a twice-daily COPD treatment, and was licensed to Sunovion in December 2016, and launched in May 2017
- Stiolto (U.S.)/Spiolto (E.U.) Respimat[®] (tiotropium combined with olodaterol) marketed by Boehringer Ingelheim for the treatment of COPD
- Bevespi Aerosphere[®] (glycopyrronium bromide in combination with formoterol fumarate) marketed by AstraZeneca
- Duaklir[®] Genuair[®] (aclidinium bromide in combination with formoterol fumarate) developed by AstraZeneca as a maintenance bronchodilator treatment for COPD and approved in November 2014 in the EU and March 2019 in the U.S.
- QMF149 (indacaterol in combination with mometasone) developed by Novartis for markets outside the U.S. and under regulatory review in the E.U. for asthma. In Phase 3 development for COPD
- Trimbow (a fixed-dose, twice daily combination of formoterol, beclomethasone and glycopyrronium) manufactured by Chiesi and indicated for use in COPD

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- Enerzair Breezehaler (QVM149) (a fixed-dose combination of indacaterol, mometasone and glycopyrronium) developed by Novartis as a triple therapy/single inhaler for the treatment of asthma and approved in the E.U., Canada, and Japan
- Breztri Aerosphere (fixed dose combination of formoterol, glycopyrronium and budesonide) developed by AstraZeneca as a triple therapy single inhaler twice-daily medication for COPD and approved in the U.S. in July 2020
- Nucala (mepolizumab; an interleukin-5 antagonist monoclonal antibody) developed by GSK for add on maintenance treatment of severe asthma in patients 12 years and older and approved in the U.S. in June 2019
- Xolair® (omalizumab, an anti-IgE antibody) developed by Genentech for patients 6 years of age and older with moderate to severe persistent asthma uncontrolled by inhaled corticosteroids and approved in 2003. Single-dose pre-filled syringes were approved by the FDA in September 2018.
- Cinqair® (anti-interleukin-5 monoclonal antibody for the add-on maintenance treatment of adults with severe asthma and an eosinophilic phenotype) marketed by TEVA Pharmaceutical Industries Ltd.
- Dupixent® (dupilumab, 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
- Fasentra® (benralizumab, an injectable anti-IL-5 monoclonal antibody) for the treatment of severe asthma in patients 12 years of age and older marketed by AstraZeneca. Fasentra Pen pre-filled auto-injector was approved by the FDA for self-administration in November 2019.
- Singulair® (monteleukast), an orally active leukotriene receptor antagonist for the prophylaxis and treatment of asthma in patients 12 months of age and older marketed by Merck
- Tezepelumab®, an injectable monoclonal antibody designed to inhibit thymic stromal lymphopoietin (TSLP), an epithelial cytokine thought to be critical in the initiation and persistence of airway inflammation. Co-developed by Astra Zeneca and Amgen for the treatment of severe asthma. Currently under regulatory review.

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® and Sandoz terminated development of generic Advair. Teva announced 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 January 2020, Astra Zeneca launched an authorized generic version of Symbicort. In general, these manufacturers are required to conduct a restricted number of clinical efficacy, pharmacokinetic and device studies to 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®.

Human Capital Resources

As of December 31, 2020, we had five employees. None of our employees are represented by a labor union. We consider our employee relations to be good. Our human capital objectives are to attract, recruit and retain top talent to manage the royalty assets with our partner, GSK, and optimize our operations and capital allocation. To support these objectives, our reward programs include equity incentive plans, bonus plan, competitive benefits and flexible working arrangements.

Information about our Executive Officers

The following table sets forth the name, age, and position of each of our executive officers as of February 25, 2021:

<u>Name</u>	<u>Age</u>	<u>Positions Held</u>
Pavel Raifeld	37	Chief Executive Officer
Marianne Zhen	52	Chief Accounting Officer

Pavel Raifeld, CFA, was appointed Chief Executive Officer in May 2020. Prior to his appointment, Mr. Raifeld, served on the investment team at Sarissa Capital Management L.P. Earlier, he was a senior member of the healthcare investment banking team at Credit Suisse Securities (USA) LLC. Previously, Mr. Raifeld worked as a consultant, primarily specializing in advising biopharmaceutical companies, at McKinsey & Company, Inc. and The Boston Consulting Group Ltd. Mr. Raifeld earned an AB degree from Harvard University and an MBA degree from Columbia University.

Marianne Zhen, CPA, 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 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.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

The Company is subject to a number of risks that if realized could affect its business, financial condition, results of operations, cash flows and access to liquidity materially. The Company’s business is subject to uncertainties and risks including:

- RELVAR[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and TRELEGY[®] 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 GSK Agreements to be less than expected, which in turn would harm our business and cause the price of our securities to fall.
- We are dependent on GSK for the successful commercialization of the products developed under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, our business would be materially harmed.
- 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.
- Our debt including our convertible subordinated notes and convertible senior notes are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect our liquidity or the amount or timing of potential distributions to our stockholders.
- We rely and will continue to rely on outsourcing arrangements for many of our activities, including financial reporting, accounting, IT and human resources.
- GSK has 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.
- We may be unable to or elect not to return capital to our stockholders.
- Our investment into the Partnership could subject us to various risks and uncertainties, any of which could impact our investment results and could materially and adversely affect our business, financial condition and results of operations.
- The Partnership Agreement limits our ability to withdraw our invested funds from the Partnership.
- Concentration of ownership by GSK may limit your ability to influence corporate matters.

Risks Related to our Business

Currently, we derive most of our revenues from GSK and our near-term success depends in large part 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 near-term success depends in large part 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;
- 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;
- 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.

When 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[®], ANORO[®] ELLIPTA[®] and TRELEGY[®] ELLIPTA[®] or a generic form of RELVAR[®]/BREO[®] ELLIPTA[®], the royalties payable to us pursuant to the GSK Agreements 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/Vectura partnership, 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 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 January 2019, Mylan announced that the FDA approved Wixela[™] Inhu[™] (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of ADVAIR DISKUS[®]. In that same month, Teva announced 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 January 2020, Astra Zeneca launched an authorized generic version of Symbicort. In December 2020, Hikma/Vectura announced that it received FDA approval and launched its generic version of GSK’s Advair Diskus[®].

In April 2016, the FDA issued draft guidance 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 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[®], or TRELEGY[®] 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 RELVAR[®]/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 former 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 any potential changes that may be proposed and what the impact, if any, will be on our business, including the 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 considered and potentially adopted, 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 evolves. For instance, in 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 the price of our securities could fall.

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[®] and 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, 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. 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 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 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® and 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 changes were to occur to any of our products, our business would be harmed, and the price of our securities could fall.

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.

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 have 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 products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of generic Advair®, GSK's approved medicine for both COPD and asthma, continue to have a negative impact on sales of RELVAR®/BREO® ELLIPTA®.

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 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® under the GSK Agreements which were assigned to TRC, while 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.

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 generally equaled the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we did 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, 2020 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 \$0.4 billion of net operating loss carryforward as of December 31, 2020. 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 an 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 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 old's, 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.

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.

Acquisitions or strategic investments we have made or may make could turn out to be unsuccessful.

As part of our strategy, we frequently monitor and analyze acquisition or investment opportunities that we believe will create value for our shareholders.

Existing or future acquisitions and investments could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of the transaction. These risks include the failure to derive any commercial value from the acquired technology, products and intellectual property including as a result of the failure to obtain regulatory approval or to monetize products once approved, as well as risks from lengthy product development and high upfront development costs without guarantee of successful results. Patents and other intellectual property rights covering acquired technology and/or intellectual property may not be obtained, and if obtained, may not be sufficient to fully protect the technology or intellectual property. We may be subject to liabilities, including unanticipated litigation costs, that are not covered by indemnification protection we may obtain. As we pursue or consummate a strategic acquisition or investment, we may value the acquired or funded company incorrectly, fail to successfully manage our operations as our asset diversity increases, expend unforeseen costs during the acquisition or integration process, or encounter other unanticipated risks or challenges. Once an investment is made, we may fail to value it accurately, properly account for it in our consolidated financial statements, or successfully divest it or otherwise realize the value which we originally invested or have subsequently reflected in our consolidated financial statements. Any failure by us to effectively limit such risks as we implement our acquisitions or strategic investments could have a material adverse effect on our business, financial condition or results of operations and may negatively impact our net income and cause the price of our securities to fall.

We have a significant amount of debt including our 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 our liquidity or the amount or timing of potential distributions to our stockholders.

As of December 31, 2020, we had \$433.5 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") and \$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"). 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.

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.

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

As of December 31, 2020, we had only five 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, accounting, IT 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.

As we continue to develop our business, including through strategic acquisitions and investments, 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 are not currently, nor do we currently intend to become, registered as an investment company under the 40 Act. We are primarily engaged, and hold ourselves as being primarily engaged, in the royalty management business and not primarily engaged in the business of investing, reinvesting or trading in securities. In addition, we monitor our mix of assets to ensure that we do not otherwise meet the definition of an investment company. Accordingly, we are not 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.

A company will generally be deemed to be an “investment company” for purposes of the Investment Company act of 1940 or the “40 Act” if:

- it is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities; or
- absent an applicable exemption or exclusion, it owns or proposes 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.

If the Company were to inadvertently meet the definition of an “investment company” and be required to register with the SEC under 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 mix of assets and sources of income.

The rules and interpretations of the SEC, the SEC staff, and the courts relating to the definition of an “investment company” under the 40 Act 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 (i) determine it to be in the Company’s and our stockholders’ interest to register as an “investment company,” and/or (ii) meet the definition of an “investment company” and be required to register with the SEC 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.

Risks Related to our Alliance with GSK

Because all our current revenues and near-term 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 near-term 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 31.6% of our outstanding common stock as of December 31, 2020, 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 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 if GSK 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 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, 2020, GSK beneficially owned approximately 31.6% 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, 2020, GSK beneficially owned approximately 31.6% 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 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.

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 is 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 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 our Strategic Partnership with Sarissa Capital

Under the Services Agreement with Sarissa Capital, we may rely on Sarissa Capital to assist in our strategic investing activity.

On December 11, 2020, we entered into the Services Agreement pursuant to which Sarissa Capital provides substantial assistance to us in connection with our acquisition strategy. Pursuant to the terms of the Services Agreement, and subject to the limitations set forth therein, Sarissa Capital will, among other things: (i) assist Innoviva in the development of an overall acquisition and investment process and strategy; (ii) advise Innoviva on market trends, market dynamics and merger and acquisition activity; (iii) identify potential transaction targets; (iv) assist in due diligence of transaction targets and the negotiation and execution of transactions; (v) advise on the growth and operational plans, performance and integration of target companies once an investment or acquisition is made; and (vi) assist in the identification of director and officer candidates for target companies. The services are provided by Sarissa Capital personnel and we have limited or no ability to control the manner upon which the services are provided. In the event that Sarissa Capital fails to adequately perform the required services, our investment activity operations and financial performance may be negatively impacted.

Our investment into the Partnership could subject us to various risks and uncertainties, any of which could impact our investment results and could materially and adversely affect our business, financial condition and results of operations.

Historically, we have invested our cash reserves in short-term investments and marketable securities, primarily corporate notes, government securities, government agencies, and commercial papers. On December 11, 2020, we entered into the Partnership Agreement and invested \$300 million of our cash reserves to be managed by Sarissa Capital as the investment manager to the Partnership.

While we expect that our revenues will continue to be primarily derived from our royalty management business, as a result of this investment, we may derive a material portion of our income from assets managed by Sarissa Capital. The investment strategy of Sarissa Capital will focus on a concentrated portfolio of “long” positions in publicly or privately traded securities (debt or equity) and derivatives of, and other financial instruments related to, each of the foregoing, specifically in the areas of healthcare, pharmaceuticals and biotechnology. The risks associated with this investment strategy may be substantially greater than the risks associated with traditional fixed-income investment strategies or other low-yield strategies.

We have limited rights to remove the general partner of the Partnership and do not have any right to participate in the management of the Partnership or the investment activity of Sarissa Capital. We are solely dependent on Sarissa Capital’s management of our investment in the Partnership. We cannot provide assurance that Sarissa Capital will be successful in meeting our investment objectives. Unexpected market volatility or losses in the Partnership’s securities portfolio could significantly and negatively affect our investment in the Partnership and therefore our investment results, financial condition or results of operations.

The Partnership Agreement limits our ability to withdraw our invested funds from the Partnership.

Under the terms of the Partnership Agreement, subject to limited exceptions, we are not entitled to withdraw our funds invested in the Partnership until expiration of a “lock-up” period. Following the expiration of the lock-up period, we are able to make annual withdrawals subject to 25% gating provision such that we would receive our entire account in the Partnership over four fiscal quarters. Therefore, we are limited in our ability to obtain liquidity with respect to those funds and are further subjects to market fluctuations with respect thereto, particularly given the expected concentrated nature of the Partnership’s portfolio.

Sarissa Capital intends to continue to manage other third party capital and is not required to dedicate any minimum amount of time to the Partnership.

In addition to managing the Partnership, Sarissa Capital, its principals and their affiliates may engage in investment and trading activities for their own accounts and/or for the accounts of third parties and is not required to afford the Partnership exclusivity or priority with respect to investment or trading activities. Affiliates of Sarissa Capital manage and expect to continue to manage other client accounts which have objectives similar to the Partnership. The Partnership Agreement does not include any specific obligations or requirements concerning allocation of time, effort or investment opportunities to us or impose any restriction on the nature or timing of investments for accounts that Sarissa Capital or its affiliates may manage.

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, 2020 and December 31, 2020, the high and low sales prices of our common stock as reported on The Nasdaq Global Select Market varied between \$7.58 and \$15.62 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 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;
- 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 or other pharmaceutical companies;
- 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 31.0% of our outstanding common stock as of December 31, 2020 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 return capital to our stockholders.

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 operations, capital requirements, execution of our strategic initiatives, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in our credit agreement 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 by GSK may limit your ability to influence corporate matters.

As of December 31, 2020, GSK beneficially owned approximately 31.6% of our outstanding common stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 0.3% of our outstanding common stock. Based on our review of publicly available filings as of December 31, 2020, our four largest stockholders other than GSK and investors affiliated with our executive officers and directors collectively owned approximately 31.3% 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.

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.

General Risks Factors

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.

Additionally, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act (“CCPA”), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Having gone into effect January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA may significantly impact our business activities and require substantial compliance costs that adversely affect business, operating results, prospects and financial condition.

Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

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 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.

Our employees or third party providers, or employees or third party providers of our portfolio companies 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 fraud or other misconduct by employees, third party providers, or employees or third party providers of our portfolio companies. Misconduct by employees, third party providers, or employees or third party providers of our portfolio companies 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 misconduct by employees, third party providers, or employees or third party providers of our portfolio companies, 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.

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.

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.

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. 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.

The widespread outbreak of an illness or any other communicable disease, or any other public health crisis, could adversely affect our business, results of operations and financial condition.

The outbreak of the novel coronavirus ("COVID-19") has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. At this time, based on the information available to us, we cannot accurately predict the extent of the impact, if any, of the COVID-19 pandemic on our royalty revenues derived from GSK upon which we significantly rely, or on the operations of our equity and other investments. The Company is closely monitoring developments related to the COVID-19 pandemic to assess its impact on the Company's business. It is possible that an extended period of global supply chain and economic disruption could materially affect our results of operations and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters consist of a lease of 2,111 square feet of office space in Burlingame, California, which expires in November 2022. We do not own or lease any other properties.

ITEM 3. LEGAL PROCEEDINGS

In May 2019, Theravance Biopharma, which is the owner of 85% of the economic interests in TRC, initiated arbitration against the Company and TRC, relating to a dispute as to the determination by Innoviva (as manager of TRC) to cause TRC to explore potential reinvestment opportunities for the royalty proceeds received by GSK into initiatives that Innoviva believes will increase the value of TRC and TRELEGY® ELLIPTA®. Theravance Biopharma alleged that, in causing TRC to not distribute substantially all royalty proceeds received from GSK, Innoviva breached the limited liability company operating agreement governing TRC (the "Operating Agreement"), as well as the fiduciary duties applicable to Innoviva as manager of TRC. The hearing in respect of the arbitration was conducted from July 23, 2019 through July 25, 2019. Post-arbitration oral argument was heard on August 14, 2019. On September 26, 2019, the arbitrator issued a final decision. The arbitrator ruled that Innoviva did not breach the Operating Agreement or its fiduciary duties by withholding royalties or pursuing reinvestment opportunities. Accordingly, the Company is permitted to continue to pursue development and commercialization initiatives. The arbitrator did conclude that Innoviva breached a provision of the Operating Agreement requiring Innoviva to deliver quarterly financial plans to Theravance Biopharma. However, the arbitrator concluded that this technical breach did not cause any damages to Theravance Biopharma and the arbitrator awarded limited injunctive relief to expand and clarify the disclosure obligations under the Operating Agreement related to the delivery of financial plans and the pursuit of investment opportunities (if those opportunities related to TRELEGY® ELLIPTA®). Finally, the arbitrator ruled that the Company is entitled to indemnification from TRC for 95% of its fees and expenses incurred in connection with the arbitration.

On September 30, 2019, the Company and TRC filed a Verified Complaint in the Court of Chancery of the State of Delaware ("Court of Chancery") to confirm the arbitration award. The award was confirmed by the Court of Chancery on May 4, 2020.

On July 16, 2020, Innoviva and TRC initiated a lawsuit in the Court of Chancery against Theravance Biopharma, seeking a permanent injunction preventing Theravance Biopharma from interfering with Innoviva's ability to cause TRC to reserve cash to pursue non-Trelegy related investment opportunities and a declaration that the arbitration award conclusively established that Innoviva, as manager of TRC, has such authority. The Court of Chancery directed the parties to obtain the arbitrator's opinion as to whether the arbitration award addressed non-Trelegy related investment opportunities. On July 31, 2020, the arbitrator, while reiterating that Innoviva has broad authority as manager of TRC, found that his award did not specifically address this situation. Accordingly, on August 5, 2020, the parties stipulated to the dismissal of the Court of Chancery action.

On October 6, 2020, Theravance Biopharma initiated a new arbitration against the Company and TRC, challenging Innoviva's authority as manager of TRC to cause TRC to pursue non-Trelegy related investment opportunities and again alleging that Innoviva is required to cause TRC to distribute substantially all royalty proceeds from GSK. An arbitration hearing is scheduled for the first quarter of 2021.

The Company intends to vigorously defend against the allegations in the new arbitration demand, but there can be no assurances that the defense will be successful.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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 12, 2021, there were 72 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, 2020.

Stock Performance Graph

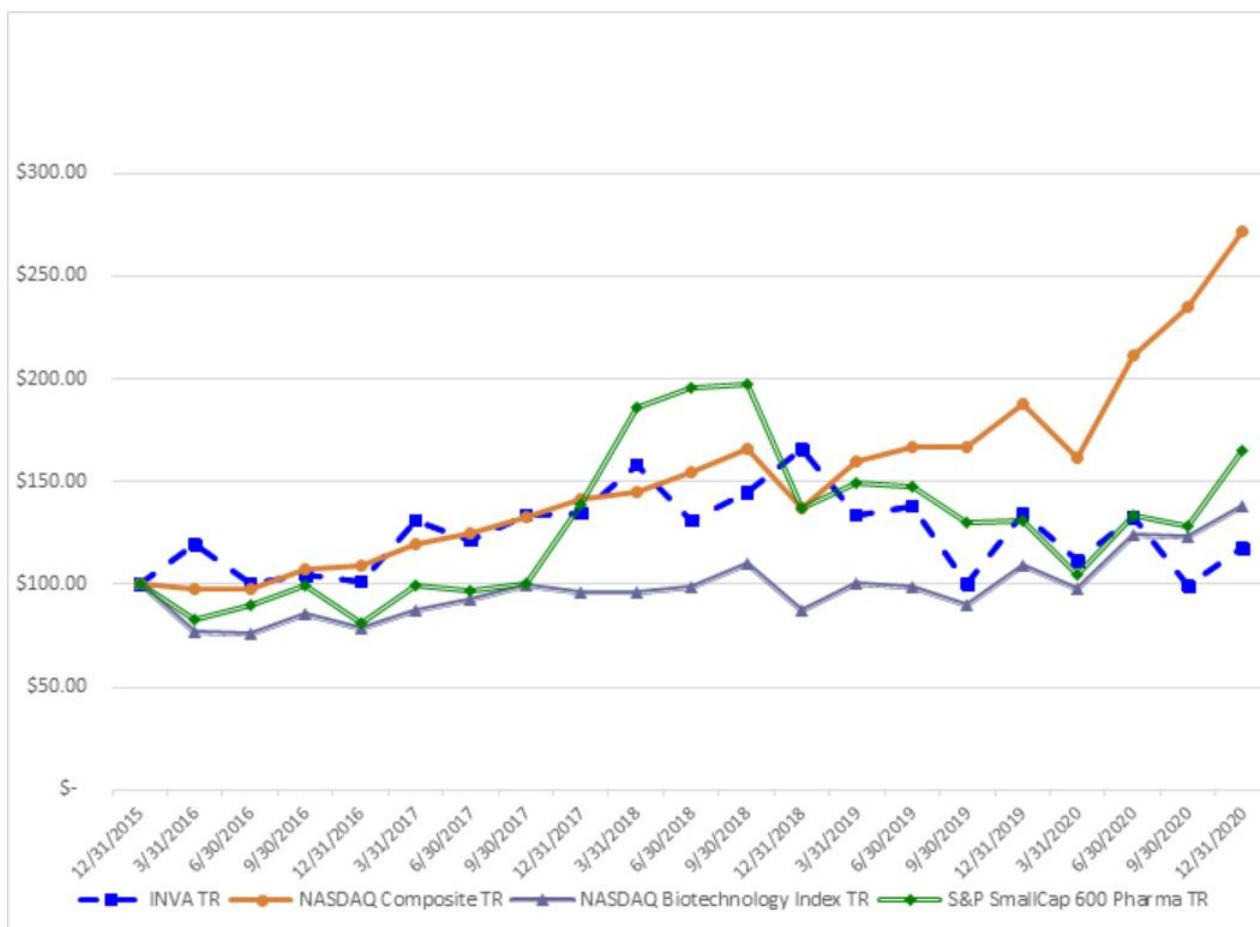
The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on December 31, 2015 and ending on December 31, 2020, with the cumulative total return of (i) the Nasdaq Composite Index, (ii) the Nasdaq S&P Small Cap 600 Pharma Index and (iii) the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of \$100.00 on December 31, 2015 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.

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, 2015 in stock or index, including reinvestment of dividends.

ITEM 6. SELECTED FINANCIAL DATA

We have early adopted the amendment to Regulation S-K Item 301 issued by the SEC effective February 10, 2021, eliminating the requirements to provide selected financial data and supplementary financial data.

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 a company with a portfolio of royalties and other healthcare assets. Our royalty portfolio contains 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 partnered with GSK, including the commercial and developmental obligations associated with the GSK Agreements, optimizing capital allocation, and providing for certain essential reporting and management functions of a public company. As of December 31, 2020, we had five employees. Our revenues consist of royalties from our respiratory partnership agreements with GSK.

Financial Highlights

In the year ended December 31, 2020, the net income attributable to Innoviva stockholders was \$224.4 million, an increase of \$67.1 million from net income of \$157.3 million in the year ended December 31, 2019, primarily due to the \$50.3 million of change in fair values of equity and other long-term investments recognized in the year ended December 31, 2020 as further described below. Cash, cash equivalents, and marketable securities totaled \$246.5 million, total value of our equity and other long-term investments was \$438.3 million, and royalty receivable was \$93.9 million as of December 31, 2020.

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, vilanterol (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. In June of 2020, GSK terminated the program and agreed to pay a \$10.0 million termination fee to TRC. This fee was recognized as revenue from collaborative arrangements with a related party on our consolidated statements of income for the year ended December 31, 2020.

Strategic Partnership with Sarissa Capital

Strategic Advisory Agreement

On December 11, 2020, we entered into a Strategic Advisory Agreement (the “Services Agreement”) with Sarissa Capital Management LP (“Sarissa Capital”), pursuant to which Sarissa Capital provides a variety of strategic services to us in order to assist us in the development and execution of our acquisition strategy. The services shall be provided free of charge to us. Sarissa Capital is considered to be a related party due to its investment in Innoviva and its representation on our Board of Directors.

Partnership Agreement

On December 11, 2020, Innoviva Strategic Partners LLC, our wholly owned subsidiary (“Strategic Partners”), entered into a subscription agreement (the “Subscription Agreement”) and an Amended and Restated Limited Partnership Agreement (the “Partnership Agreement”) pursuant to which Strategic Partners became a limited partner of ISP Fund LP (the “Partnership”). The general partner of the Partnership (the “General Partner”) is an affiliate of Sarissa Capital and, pursuant to an investment management agreement, Sarissa Capital acts as the investment adviser to the Partnership. Strategic Partners made a \$300 million initial contribution into the Partnership. The Partnership was formed for the purposes of investing in “long-only” securities in the healthcare, pharmaceutical and biotechnology industries. The Partnership Agreement provides for Sarissa Capital to receive a customary one percent management fee from the Partnership, payable quarterly in advance, measured based on the Net Asset Value of Strategic Partners’ capital account in the Partnership. In addition, the General Partner is entitled to a customary 10% annual performance allocation based on the Net Profits of the Partnership during the annual measurement period. The Partnership Agreement includes a lock-up period of thirty-six months after which Strategic Partners is entitled to make withdrawals from the Partnership as of such lock-up expiration date and each anniversary thereafter, subject to certain limitations.

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 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.

Revenue Recognition

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. We recognize our royalty revenue on 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 \$326.8 million for the year ended December 31, 2020 and \$261.0 million for each of the years ended December 31, 2019 and 2018. We also recognized a \$10.0 million termination fee related to the MABA program with GSK as revenue from collaborative arrangements with a related party on our consolidated statements of income for the year ended December 31, 2020.

Capitalized Fees paid to a Related Party

We capitalize fees paid to licensors related to agreements for certain approved products or commercialized products (“Capitalized Fees”). Our gross Capitalized Fees of \$220.0 million as of December 31, 2020 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 Collaboration 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, 2020, 2019, and 2018 was \$13.8 million. The remaining estimated amortization expense is \$13.8 million for each of the years from 2021 to 2025 and \$56.3 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, 2020.

Variable Interest Entities

We evaluate our ownership, contractual and other interest in the entities that we invest in to determine if they are variable interest entities (“VIEs”), whether we have a variable interest in those entities and the nature and extent of those interests. Such evaluation is performed continually throughout the entire period when we stay involved with these entities. Based on our evaluation, if we determine we are the primary beneficiary of a VIE, we consolidate the entity’s financial results into our financial statements.

We consolidate the financial results of TRC and Pulmoquine Therapeutics, Inc. (“Pulmoquine”), which we have determined to be VIEs, because we have the power to direct the economically significant activities of these entities and the obligation to absorb losses of, or the right to receive benefits from them, and we are the primary beneficiary of the entities. We also consolidate the financial results of ISP Fund LP that we partner with Sarissa Capital because we have determined that the Partnership is a VIE and Strategic Partners is the primary beneficiary of this VIE.

Equity and Other Long-Term Investments

As part of our capital allocation strategies, we invest from time to time in equity securities of private or public companies. We also enter into strategic partnerships in order to accelerate the execution of our strategy and enhance returns on our capital. If we determine that we have control over these companies or partnerships, we consolidate the financial statements of the company or partnership. If we determine that we do not have control over these companies or partnerships under either voting or VIE models, we then determine if we have an ability to exercise significant influence via voting interests, board representation or other business relationships.

We may account for the equity investments where we exercise significant influence using either an equity method of accounting or at fair value by electing the fair value option under Accounting Standards Codification (“ASC”) Topic 825, *Financial Instruments*. If the fair value option is applied to an investment that would otherwise be accounted for under the equity method, we apply it to all our financial interests in the same entity (equity and debt, including guarantees) that are eligible items. All gains and losses from fair value changes, unrealized and realized, are presented as changes in fair values of equity investments, net on the consolidated statements of income.

If we conclude that we do not have an ability to exercise significant influence over an investee, we may elect to account for an equity security without a readily determinable fair value using the measurement alternative as prescribed by ASC Topic 825. This measurement alternative allows us to measure the equity investment at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

Equity investments in common stock and warrants of Armata Pharmaceuticals, Inc. (NYSE American: ARMP) (“Armata”) and Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX) (“Entasis”) are accounted for at fair value. The equity investments are included in equity and other long-term investments on the consolidated balance sheets.

In October of 2020, TRC acquired 20,469,432 shares of Series C preferred stock and warrants to purchase 5,117,358 shares of InCarda Therapeutics Inc. (“InCarda”) in the total amount of \$15.0 million. The Series C preferred stock is accounted for using the measurement alternative and the warrants are recorded at fair value using the Black-Scholes-Merton pricing model. The InCarda Series C preferred stock and warrants are included in equity and other long-term investments on the consolidated balance sheets.

Investments held in the ISP Fund LP by Strategic Partners pursuant to the Partnership Agreement are accounted for at fair value and included in equity and other long-term investments on our consolidated balance sheets.

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.

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 7, “Stock-Based Compensation,” to the consolidated financial statements appearing in this Annual Report on Form 10-K.

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.

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:

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
Royalties from a related party — RELVAR/BREO	\$ 221,536	\$ 189,424	\$ 220,162	\$ 32,112	17 %	\$ (30,738)	(14)%
Royalties from a related party — ANORO	45,992	42,625	41,286	3,367	8	1,339	3
Royalties from a related party — TRELEGY	73,089	42,790	13,379	30,299	71	29,411	*
Total royalties from a related party	340,617	274,839	274,827	65,778	24	12	—
Less: amortization of capitalized fees paid to a related party	(13,823)	(13,823)	(13,823)	—	—	—	—
Royalty revenue	326,794	261,016	261,004	65,778	25	12	—
Strategic alliance — MABA program	10,000	—	—	10,000	—	—	—
Total net revenue from GSK	\$ 336,794	\$ 261,016	\$ 261,004	\$ 75,778	29 %	\$ 12	— %

* Not Meaningful

Total net revenue increased to \$336.8 million for the year ended December 31, 2020, compared to the year ended December 31, 2019. Royalties for RELVAR[®]/BREO[®] ELLIPTA[®] increased due to favorable adjustments from better than expected pricing and continued volume growth in both the U.S. and non-U.S. markets. ANORO[®] ELLIPTA[®] maintained its steady volume growth, offset by the increasing pricing pressure in the U.S. Royalties for TRELEGY[®] ELLIPTA[®] were higher due to the continued growth in prescriptions and market share.

Total net revenue increased slightly for the year ended December 31, 2019, compared to the year ended December 31, 2018. Royalties for RELVAR[®]/BREO[®] ELLIPTA[®] decreased primarily due to increased pricing pressure in the U.S., offset by volume growth in both the U.S. and non-U.S. markets. The decrease was offset by continued growth in prescriptions and market share for TRELEGY[®] ELLIPTA[®]. Royalties for ANORO[®] ELLIPTA[®] increased slightly year over year.

Research & Development

Research and development (“R&D”) expenses of \$1.8 million for the year ended December 31, 2020 were attributable to Pulmoquine’s product development efforts.

We did not incur R&D expenses during the years ended December 31, 2019 and 2018.

General & Administrative

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

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
General and administrative	\$ 13,883	\$ 14,656	\$ 20,053	\$ (773)	(5)%	\$ (5,397)	(27)%
General and administrative - related party	—	—	2,700	—	*	(2,700)	*

* Not Meaningful

General and administrative expenses decreased by \$0.8 million for the year ended December 31, 2020, compared to the year ended December 31, 2019, mainly attributable to lower operating expenses incurred. The amount for the year ended December 31, 2020 included \$2.1 million fees related to due diligence efforts associated with various investments and \$1.7 million legal and related fees for the arbitration initiated by Theravance Biopharma against the Company and TRC.

General and administrative expenses decreased by \$5.4 million for the year ended December 31, 2019, compared to the year ended December 31, 2018, mainly attributable to lower personnel-related expenses as a result of lower headcount. The amount for the year ended December 31, 2019 included \$3.1 million legal and related fees for the arbitration initiated by Theravance Biopharma against the Company and TRC, of which \$3.0 million was accounted for as TRC’s expenses and consolidated in the Company’s consolidated statements of income.

The amount 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.

Other Expense, net, and Interest Income

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

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
Other expense, net	\$ (348)	\$ (345)	\$ (5,702)	\$ (3)	1 %	\$ 5,357	* %
Interest income	1,524	5,540	1,660	(4,016)	(72)	3,880	*

* 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.

Interest income decreased for the year ended December 31, 2020, compared to the years ended December 31, 2019 and 2018, primarily due to lower interest rates resulting from the COVID-19 pandemic.

Interest Expense

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

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
Interest expense	\$ 18,331	\$ 18,660	\$ 23,954	\$ (329)	(2)	\$ (5,294)	(22)%

Interest expense decreased slightly for the year ended December 31, 2020, compared to the prior years primarily due to the lower average outstanding debt balance. See “Liquidity” section below for further information.

Changes in Fair Values of Equity and Long-Term Investments

The changes in fair values of equity and long-term investments of \$50.3 million for the year ended December 31, 2020 reflect the net unrealized gain in the stock and warrants of our investments in Armata, Entasis, and InCarda, and those equity investments managed by ISP Fund LP.

Income Taxes

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

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
Income tax benefit (expense), net	\$ (60,431)	\$ (41,902)	\$ 196,073	\$ (18,529)	44	\$ (237,975)	*

* Not Meaningful

As of December 31, 2020, 2019 and 2018, we had net operating loss carryforwards for federal income taxes of \$0.4 billion, \$0.6 billion, and \$0.8 billion, respectively. As of December 31, 2020, 2019 and 2018, we had federal research and development tax credit carryforwards of \$43.6 million, \$44.4 million, and \$44.8 million, respectively.

For the year ended December 31, 2020 and 2019, we recognized \$60.4 million and \$41.9 million of income tax expense, respectively, based on the taxable income generated during those years.

For the year ended December 31, 2018, we released our valuation allowance on deferred tax assets and recognized \$196.1 million of income tax benefit. We had total unrecognized tax benefits of \$15.2 million as of December 31, 2020. Total unrecognized tax benefits that, if recognized, would affect our effective tax rate were \$8.0 million as of December 31, 2020. Our total unrecognized tax benefits as of December 31, 2019 and 2018 were \$15.3 million and \$15.4 million, respectively.

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. We conducted an analysis through September 30, 2020 to determine whether an ownership change had occurred since inception. The study concluded that it is more likely than not that the Company did not experience an ownership change during the testing period. 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:

(In thousands)	Year Ended December 31,			Change			
	2020	2019	2018	2020		2019	
	\$	\$	\$	\$	%	\$	%
Net income attributable to noncontrolling interest	\$ 69,412	\$ 33,705	\$ 11,272	\$ 35,707	*	\$ 22,433	*

* Not Meaningful

Net income attributable to noncontrolling interest represents the 85% share of net income in Theravance Respiratory Company, LLC for Theravance Biopharma. The year over year increases were primarily due to 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, 2020, we generated gross royalty revenues from GSK of \$340.6 million. Net cash and cash equivalents, short-term investments and marketable securities totaled \$246.5 million, and royalties receivable from GSK totaled \$93.9 million, as of December 31, 2020.

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured convertible subordinated notes, which will mature on January 15, 2023. In connection with the offering of the 2023 Notes, we entered into two privately negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the initial conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share, both of which are subject to adjustments consistent with the 2023 Notes. As a result of the partial conversion by certain holders of the 2023 Notes in July 2014, and dividends declared and paid in 2014 and 2015, the conversion rate was adjusted in total to 50.5818 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents a conversion price of approximately \$19.77 per share. As a result of the conversion rate adjustments, the capped call strike price and cap price were also adjusted to \$19.77 and \$27.04, respectively. For the year ending December 31, 2016, we retired a portion of our 2023 Notes with a face value of \$14.1 million and carrying value of \$13.9 million by way of purchase in the open market.

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 was fully paid off in December 2019, almost three years ahead of its maturity in 2022.

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 allowable with the terms of our debt agreements.

Cash Flows

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

(In thousands)	Year Ended December 31,			Change	
	2020	2019	2018	2020	2019
Net cash provided by operating activities	\$ 313,113	\$ 257,458	\$ 223,531	\$ 55,655	\$ 33,927
Net cash provided by (used in) investing activities	(314,937)	(18,003)	3,519	(296,934)	(21,522)
Net cash used in financing activities	(29,785)	(23,776)	(237,969)	(6,009)	214,193

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2020 was \$313.1 million, consisting primarily of our net income of \$293.8 million, adjusted for non-cash items such as \$60.4 million of deferred income taxes, \$13.8 million of depreciation and amortization, \$8.4 million amortization of debt discount and issuance costs, \$1.7 million of stock-based compensation expense, partially offset by a \$50.3 million increase in the fair values of our equity investments and an increase in receivables from collaborative arrangements of \$14.5 million.

Cash provided by operating activities for the year ended December 31, 2019 was \$257.5 million, consisting primarily of our net income of \$191.0 million, adjusted for non-cash items such as \$41.9 million of deferred income taxes, \$13.9 million of depreciation and amortization, \$7.8 million amortization of debt discount and issuance costs, \$2.1 million of stock-based compensation expense, partially offset by \$2.2 million of amortization of discount on short-term investments and a decrease in receivables from collaborative arrangements of \$3.9 million.

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 Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 of \$314.9 million was primarily due to \$400.9 million in purchases of common stock, warrants, money market funds and other marketable securities, partially offset by \$86.0 million of proceeds received from maturities of marketable securities.

Net cash used in investing activities for the year ended December 31, 2019 of \$18.0 million was primarily due to \$231.9 million in purchases of marketable securities, partially offset by \$213.9 million of proceeds received from maturities of marketable securities.

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.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2020 of \$29.8 million was primarily due to \$30.5 million distributions to noncontrolling interest.

Net cash used in financing activities for the year ended December 31, 2019 of \$23.8 million was primarily due to \$13.8 million payment for paying off the remaining principal balance of our Term B Loan and \$10.6 million distributions to noncontrolling interest.

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.

Off-Balance Sheet Arrangements

In June 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma. However, if Theravance Biopharma had defaulted on its lease obligations, we would have been held liable by the landlord and thus, we had in substance guaranteed the lease payments for these facilities, as well as lease-related payments including utilities, property taxes, and common area maintenance. This lease concluded in May 2020, and we have no further obligations for the lease.

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, 2020.

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, 2020.

(In thousands)	Total	Payment Due by Period			
		Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
2023 Notes	\$ 253,786	\$ 5,121	\$ 248,665	\$ —	\$ —
2025 Notes	216,563	4,813	9,625	202,125	—
Facility lease	232	123	109	—	—
Total	<u>\$ 470,581</u>	<u>\$ 10,057</u>	<u>\$ 258,399</u>	<u>\$ 202,125</u>	<u>\$ —</u>

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 is not material as all investments other than equity investments were in money market funds as of December 31, 2020.

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, 2020, based on available pricing information, the fair values of our 2023 Notes and 2025 Notes were estimated to be \$239.8 million and \$206.1 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 246,487	\$ 278,096
Short-term marketable securities	—	72,749
Related party receivables from collaborative arrangements	93,931	79,427
Prepaid expenses and other current assets	1,640	962
Total current assets	<u>342,058</u>	<u>431,234</u>
Property and equipment, net	28	33
Equity and other long-term investments	438,258	—
Capitalized fees paid to a related party, net	125,253	139,076
Deferred tax assets, net	93,759	154,171
Other assets	214	312
Total assets	<u>\$ 999,570</u>	<u>\$ 724,826</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 66	\$ 10
Accrued personnel-related expenses	490	647
Accrued interest payable	4,152	4,152
Other accrued liabilities	1,402	562
Total current liabilities	<u>6,110</u>	<u>5,371</u>
Long-term debt, net of discount and issuance costs	385,517	377,120
Other long-term liabilities	106	219
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: \$0.01 par value, 230 shares authorized, no shares issued and outstanding	—	—
Common stock: \$0.01 par value, 200,000 shares authorized, 101,392 and 101,288 issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	1,014	1,013
Additional paid-in capital	1,260,900	1,258,859
Accumulated other comprehensive income	—	27
Accumulated deficit	(722,002)	(946,404)
Total Innoviva stockholders' equity	<u>539,912</u>	<u>313,495</u>
Noncontrolling interest	67,925	28,621
Total stockholders' equity	<u>607,837</u>	<u>342,116</u>
Total liabilities and stockholders' equity	<u>\$ 999,570</u>	<u>\$ 724,826</u>

See accompanying notes to consolidated financial statements.

INNOVIVA, INC.

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Year Ended December 31,		
	2020	2019	2018
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, 2020, 2019, 2018, respectively	\$ 326,794	\$ 261,016	\$ 261,004
Revenue from collaborative arrangements with a related party	10,000	—	—
Total net revenue	336,794	261,016	261,004
Operating expenses:			
Research and development	1,788	—	—
General and administrative	13,883	14,656	20,053
General and administrative - related party	—	—	2,700
Total operating expenses	15,671	14,656	22,753
Income from operations	321,123	246,360	238,251
Other expense, net	(348)	(345)	(5,702)
Interest income	1,524	5,540	1,660
Interest expense	(18,331)	(18,660)	(23,954)
Changes in fair values of equity investments	50,277	—	—
Income before income taxes	354,245	232,895	210,255
Income tax benefit (expense), net	(60,431)	(41,902)	196,073
Net income	293,814	190,993	406,328
Net income attributable to noncontrolling interest	69,412	33,705	11,272
Net income attributable to Innoviva stockholders	\$ 224,402	\$ 157,288	\$ 395,056
Basic net income per share attributable to Innoviva stockholders	\$ 2.21	\$ 1.55	\$ 3.92
Diluted net income per share attributable to Innoviva stockholders	\$ 2.02	\$ 1.43	\$ 3.53
Shares used to compute Innoviva basic and diluted net income per share:			
Shares used to compute basic net income per share	101,320	101,150	100,849
Shares used to compute diluted net income per share	113,554	113,409	113,408

See accompanying notes to consolidated financial statements.

INNOVIVA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(In thousands)

	Year Ended December 31,		
	2020	2019	2018
Net income	\$ 293,814	\$ 190,993	\$ 406,328
Unrealized gain on marketable securities, net	—	30	15
Reclassifications to net income	(27)	—	—
Comprehensive income	293,787	191,023	406,343
Comprehensive income attributable to noncontrolling interest	69,412	33,705	11,272
Comprehensive income attributable to Innoviva stockholders	<u>\$ 224,375</u>	<u>\$ 157,318</u>	<u>\$ 395,071</u>

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount				Shares	Amount		
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, net of repurchase of shares to satisfy tax withholding	(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
Distributions to noncontrolling interest	—	—	—	—	—	—	—	(10,553)	(10,553)
Exercise of stock options, and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	190	2	536	—	—	—	—	—	538
Stock-based compensation	—	—	2,056	—	—	—	—	—	2,056
Net income	—	—	—	—	157,288	—	—	33,705	190,993
Other comprehensive income	—	—	—	30	—	—	—	—	30
Balance as of December 31, 2019	101,288	\$ 1,013	\$ 1,258,859	\$ 27	\$ (946,404)	—	\$ —	\$ 28,621	\$ 342,116
Distributions to noncontrolling interest	—	—	—	—	—	—	—	(30,474)	(30,474)
Equity activity of noncontrolling interest from a consolidated variable interest entity	—	—	—	—	—	—	—	366	366
Exercise of stock options, and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	104	1	343	—	—	—	—	—	344
Stock-based compensation	—	—	1,698	—	—	—	—	—	1,698
Net income	—	—	—	—	224,402	—	—	69,412	293,814
Other comprehensive income	—	—	—	(27)	—	—	—	—	(27)
Balance as of December 31, 2020	101,392	\$ 1,014	\$ 1,260,900	\$ —	\$ (722,002)	—	\$ —	\$ 67,925	\$ 607,837

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2020	2019	2018
Cash flows from operating activities			
Net income	\$ 293,814	\$ 190,993	\$ 406,328
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred income taxes	60,420	41,875	(196,054)
Depreciation and amortization	13,840	13,874	13,872
Stock-based compensation	1,698	2,056	3,233
Amortization of debt discount and issuance costs	8,397	7,799	7,748
Loss on write-off of property and equipment	—	104	—
Loss on extinguishment of debt	—	216	5,745
Amortization of discount on short-term investments	(343)	(2,229)	(256)
Amortization of lease guarantee	(135)	(325)	(325)
Changes in fair values of equity investments	(50,277)	—	—
Other non-cash items	21	—	—
Changes in operating assets and liabilities:			
Receivables from collaborative arrangements	(14,504)	3,859	(12,746)
Prepaid expenses and other current assets	(678)	(113)	(95)
Other assets	—	27	—
Accounts payable	56	(1)	(590)
Accrued personnel-related expenses and other accrued liabilities	804	(439)	(1,677)
Accrued interest payable	—	(112)	(1,656)
Other long-term liabilities	—	(126)	4
Net cash provided by operating activities	<u>313,113</u>	<u>257,458</u>	<u>223,531</u>
Cash flows from investing activities			
Maturities of marketable securities	86,000	213,924	75,375
Purchases of marketable securities	(12,943)	(231,915)	(71,856)
Purchases of equity and other long term investments	(387,981)	—	—
Purchases of property and equipment	(13)	(12)	—
Net cash provided by (used in) investing activities	<u>(314,937)</u>	<u>(18,003)</u>	<u>3,519</u>
Cash flows from financing activities			
Repurchase of shares to satisfy tax withholding	(92)	(89)	(3,073)
Payments of principal on senior secured term loans	—	(13,750)	(230,000)
Payments of cash dividends to stockholders	—	(11)	(80)
Proceeds from issuances of common stock, net	436	627	1,139
Net proceeds from the issuance of variable interest entity's equity	345	—	—
Distributions to noncontrolling interest	(30,474)	(10,553)	(5,955)
Net cash used in financing activities	<u>(29,785)</u>	<u>(23,776)</u>	<u>(237,969)</u>
Net increase (decrease) in cash and cash equivalents	<u>(31,609)</u>	<u>215,679</u>	<u>(10,919)</u>
Cash and cash equivalents at beginning of period	<u>278,096</u>	<u>62,417</u>	<u>73,336</u>
Cash and cash equivalents at end of period	<u>\$ 246,487</u>	<u>\$ 278,096</u>	<u>\$ 62,417</u>
Supplemental disclosure of cash flow information			
Cash paid for interest	\$ 9,933	\$ 10,974	\$ 17,861

See accompanying notes to consolidated financial statements.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Operations

Innoviva (referred to as “Innoviva”, the “Company”, or “we” and other similar pronouns) is a company with a portfolio of royalties and other healthcare assets. Our royalty portfolio contains 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[®].

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Innoviva and its wholly owned subsidiaries and variable interest entities for which we are the primary beneficiary. All intercompany balances and transactions have been eliminated in consolidation. For the consolidated variable interest entities, we record net income attributable to noncontrolling interest on our consolidated statements of income equal to the percentage of ownership interest retained in such entity by the respective noncontrolling party.

Use of Management’s Estimates

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles (“GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates. Management evaluates its significant accounting policies and estimates on an ongoing basis. We base our estimates on historical experience and other relevant assumptions that we believe to be reasonable under the circumstances. These estimates also form the basis for making judgments about the carrying values of assets and liabilities when these values are not readily apparent from other sources.

Certain Risks and Concentrations

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities and equity investments. Although we deposit our cash with multiple financial institutions, our deposits, at times, may exceed federally insured limits. Refer to “Segment Reporting” below for concentrations with respect to revenues and geographic locations.

Segment Reporting

We operate in a single segment, which is to provide capital return to stockholders by maximizing the potential value of our respiratory assets partnered with GSK. Revenues are generated from our collaborative arrangements and royalty payments from GSK, located in Great Britain. Our facilities are located within the United States.

Variable Interest Entities

We evaluate our ownership, contractual and other interest in entities to determine if they are variable interest entities (“VIE”), whether we have a variable interest in those entities and the nature and extent of those interests. Based on our evaluation, if we determine we are the primary beneficiary of a VIE, we consolidate the entity in our financial statements.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cash and Cash Equivalents

We consider all highly liquid investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

Investments in Marketable Securities

We invest in short-term investments and marketable securities, primarily corporate notes, government securities, government agencies, and government commercial papers. We limit the amount of credit exposure with any one issuer, industry or geographic area for investments other than instruments backed by the U.S. federal government. We classify our marketable securities as available-for-sale securities and report them at fair value in cash equivalents or short-term marketable securities on the consolidated balance sheets with related unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations. Realized gains and losses, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

We regularly review all of our investments for other-than-temporary declines in estimated fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. When we determine that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, we reduce the carrying value of the security and record a loss for the amount of such decline to other income (expense), net.

Equity Investments

We invest from time to time in equity securities of private or public companies. If we determine that we have control over these companies, we include them in our consolidated financial statements. If we determine that we do not have control over these companies under either voting or VIE models, we then determine if we have an ability to exercise significant influence via voting interests, board representation or other business relationships.

We may account for the equity investments where we exercise significant influence using either an equity method of accounting or at fair value by electing the fair value option under Accounting Standards Codification ("ASC") Topic 825, *Financial Instruments*. If the fair value option is applied to an investment that would otherwise be accounted for under the equity method, we apply it to all our financial interests in the same entity (equity and debt, including guarantees) that are eligible items. All gains and losses from fair value changes, unrealized and realized, are presented as changes in fair values of equity investments, net on the consolidated statements of income.

If we conclude that we do not have an ability to exercise significant influence over an investee, we may elect to account for an equity security without a readily determinable fair value using the measurement alternative described in ASC Topic 825. This measurement alternative allows us to measure the equity investment at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

Fair Value of Financial Instruments

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

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify these inputs into the following hierarchy:

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

Level 2—Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

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

Financial instruments include cash equivalents, marketable securities, receivables from collaborative arrangements, accounts payable, and accrued liabilities. Cash equivalents and marketable securities are carried at estimated fair value. The carrying values of receivables from collaborative arrangements, accounts payable, and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments.

Property and Equipment

Property and equipment, which consisted of equipment, computer equipment, software, office furniture and fixtures, was immaterial as of December 31, 2020 and 2019, respectively.

Property, equipment and leasehold improvements are stated at cost and depreciated using the straight-line method as follows:

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

Capitalized Fees Paid to a Related Party

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as capitalized fees paid to a related party (“Capitalized Fees”) and amortize them on a straight-line basis over their estimated useful lives upon the commercial launch of the product, shortly after its regulatory approval. The estimated useful lives of these Capitalized Fees are determined 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 Collaboration 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. 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.

Revenue Recognition

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.

We recognize the royalty revenue on 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.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Fair Value of Stock-Based Compensation Awards

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under our equity incentive plans and rights to acquire stock granted under our employee stock purchase plan (“ESPP”). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected 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.

Restricted stock units (“RSUs”) and restricted stock awards (“RSAs”) are measured based on the fair market values of the underlying stock on the dates of grant.

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

The estimated fair value of stock options, RSUs and RSAs is expensed on a ratable or straight-line basis over the expected term of the grant or expected term of the vesting, and the estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once we have determined that it is probable that performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded 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 milestones 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.

Compensation expense for purchases under the ESPP is recognized based on the fair value of the common stock on the date of offering, less the purchase discount percentage provided for in the plan.

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 the 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.

The recognition and measurement of 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 and deferred tax assets will be realized 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.

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

Comprehensive Income

Comprehensive income is comprised of net income and other comprehensive income (loss). Other comprehensive income (loss) consists of changes in unrealized and realized gains and losses on our marketable securities and the related tax impact of these changes.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Related Parties

GSK owned 31.6% of our outstanding common stock as of December 31, 2020. Transactions with GSK are described in Note 3, “Collaborative Arrangements.”

Sarissa Capital owned 6.3% of our outstanding common stock as of December 31, 2020. Transactions with Sarissa Capital are described in Note 4, “Consolidated Entities”. Sarissa Capital is considered to be a related party because two of its principals are members of our Board of Directors.

Recently Adopted Accounting Standards Updates

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-13 *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, as clarified in subsequent amendments to the initial guidance (collectively, “Topic 326”). Topic 326 requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecast. We adopted ASC 326 using a modified retrospective approach which requires a cumulative effect adjustment as of the beginning of the reporting period in which the guidance is adopted. Topic 326 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We adopted Topic 326 effective January 1, 2020. The adoption did not have a material impact on our consolidated financial statements.

Recently Issued Accounting Standards or Updates Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We do not expect the adoption of ASU 2019-12 to have a material impact on our consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which is intended to simplify the accounting for convertible instruments by removing certain separation models in Subtopic 470-20 for convertible instruments. The ASU is effective for fiscal years beginning after December 15, 2021, and for interim periods within those fiscal years with early adoption permitted. We are currently in the process of evaluating the effects of the provisions of ASU 2020-06 on our consolidated financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*. ASU 2020-10 contains improvements to the Codification by ensuring that all guidance that requires or provides an option for an entity to provide information in the notes to financial statements is codified in the disclosure section of the Codification. The ASU also improves various topics in the Codification so that entities can apply guidance more consistently on codifications that are varied in nature where the original guidance may have been unclear. The amendments in ASU 2020-10 are effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. We do not expect the adoption of ASU 2020-10 to have a material impact on our consolidated financial statements and related disclosures.

2. NET INCOME PER SHARE

Basic net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock outstanding. Diluted net income per share attributable to Innoviva stockholders is computed by dividing net income attributable to Innoviva stockholders by the weighted-average number of shares of common stock and dilutive potential common stock equivalents then outstanding. Dilutive potential common stock equivalents include the assumed exercise, vesting and issuance of employee stock awards using the treasury stock method, as well as common stock issuable upon assumed conversion of our convertible subordinated notes due 2023 (the “2023 Notes”) using the if-converted method.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our convertible senior notes due 2025 (the “2025 Notes”) are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election. Our current intent is to settle the principal amount of the 2025 Notes in cash upon conversion. The impact of the assumed conversion premium to diluted net income per share is computed using the treasury stock method. As the average market price per share of our common stock as reported on The Nasdaq Global Select Market was lower than the initial conversion price of \$17.26 per share, there was no dilutive effect of the assumed conversion premium for the years ended December 31, 2020, 2019, and 2018 respectively.

The following table shows the computation of basic and diluted net income per share for the years ended December 31, 2020, 2019 and 2018:

(In thousands except per share data)	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net income attributable to Innoviva stockholders, basic	\$ 224,402	\$ 157,288	\$ 395,056
Add: interest expense on 2023 Notes	4,717	4,648	5,661
Net income attributable to Innoviva stockholders, diluted	<u>\$ 229,119</u>	<u>\$ 161,936</u>	<u>\$ 400,717</u>
Denominator:			
Weighted-average shares used to compute basic net income per share attributable to Innoviva stockholders	101,320	101,150	100,849
Dilutive effect of 2023 Notes	12,189	12,189	12,189
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	45	70	370
Weighted-average shares used to compute diluted net income per share attributable to Innoviva stockholders	<u>113,554</u>	<u>113,409</u>	<u>113,408</u>
Net income per share attributable to Innoviva stockholders			
Basic	<u>\$ 2.21</u>	<u>\$ 1.55</u>	<u>\$ 3.92</u>
Diluted	<u>\$ 2.02</u>	<u>\$ 1.43</u>	<u>\$ 3.53</u>

Anti-dilutive Securities

The following common stock equivalents were not included in the computation of diluted net income per share because their effect was anti-dilutive:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	1,193	1,130	1,490

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. REVENUE RECOGNITION AND COLLABORATIVE ARRANGEMENTS

Revenue from Collaborative Arrangements

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Royalties from a related party - RELVAR/BREO	\$ 221,536	\$ 189,424	\$ 220,162
Royalties from a related party - ANORO	45,992	42,625	41,286
Royalties from a related party - TRELEGY	73,089	42,790	13,379
Total royalties from a related party	340,617	274,839	274,827
Less: amortization of capitalized fees paid to a related party	(13,823)	(13,823)	(13,823)
Royalty revenue	326,794	261,016	261,004
Strategic alliance - MABA program	10,000	—	—
Total net revenue from GSK	\$ 336,794	\$ 261,016	\$ 261,004

LABA Collaboration

As a result of the launch and approval of RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®] in the U.S., Japan and Europe, we paid milestone fees to GSK totaling \$220.0 million during the year ended December 31, 2014. 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 product. The amortization expense is recorded as a reduction to the royalties from GSK.

We are entitled to receive annual 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. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. 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

During the year ended December 31, 2020, we recognized \$10.0 million in revenue from a termination fee paid in connection with the termination of the Bifunctional Muscarinic Antagonist-Beta2 Agonist (“MABA”) program under the Strategic Alliance Agreement with GSK.

4. CONSOLIDATED ENTITIES

We consolidate the financial results of TRC and Pulmoquine Therapeutics, Inc. (“Pulmoquine”), which we have determined to be VIEs. As we have the power to direct the economically significant activities of these entities and the obligation to absorb losses of, or the right to receive benefits from them, and we are the primary beneficiary of the entities. We also consolidate the financial results of ISP Fund LP (the “Partnership”), our partnership with Sarissa Capital, as we have determined that the Partnership is a VIE and we are its primary beneficiary.

Theravance Respiratory Company, LLC

The primary source of revenue for TRC is the royalties generated from the net sales of TRELEGY[®] ELLIPTA[®] by GSK. As of December 31, 2020, TRC held an equity investment in InCarda Therapeutics, Inc. (“InCarda”). Refer to Note 5, “Financial Instruments and Fair Value Measurements,” for more information.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The summarized financial information for TRC is presented as follows:

Balance sheets

(In thousands)	December 31,	
	2020	2019
Assets		
Cash and cash equivalents	\$ 38,081	\$ 22,339
Receivables from collaborative arrangements	24,946	14,388
Prepaid expenses and other current assets	—	10
Equity and other long-term investments	16,959	—
Total assets	<u>79,986</u>	<u>36,737</u>
Liabilities and LLC Members' Equity		
Current liabilities	508	3,069
LLC members' equity	79,478	33,668
Total liabilities and LLC members' equity	<u>\$ 79,986</u>	<u>\$ 36,737</u>

Income statements

(In thousands)	Year Ended December 31,	
	2020	2019
Royalty revenue from a related party	\$ 73,089	\$ 42,790
Revenue from collaborative arrangements	10,000	—
Total revenue	<u>83,089</u>	<u>42,790</u>
Operating expenses	<u>2,612</u>	<u>3,380</u>
Income from operations	80,477	39,410
Other income (expense), net	38	243
Changes in fair values of equity investments	1,147	—
Net Income	<u>\$ 81,662</u>	<u>\$ 39,653</u>

Pulmoquine Therapeutics, Inc.

On April 20, 2020, we entered into a securities purchase agreement with Pulmoquine to purchase 5,808,550 shares of Series A preferred stock for \$5.0 million in cash. Upon consummation of the transaction, we owned approximately 90.9% of Pulmoquine's outstanding shares (excluding unvested restricted shares) and hold a majority voting interest. Pulmoquine is a biotechnology company focused on the research and development of an aerosolized formulation of hydroxychloroquine to treat respiratory infections. As of December 31, 2020, total assets attributable to Pulmoquine were \$3.5 million, including \$3.2 million in cash and cash equivalents and \$0.3 million in current assets. Pulmoquine does not currently generate revenue. The net loss for the year ended December 31, 2020, was \$2.2 million, including total operating expenses of \$2.0 million.

ISP Fund LP

On December 11, 2020, we entered into a Strategic Advisory Agreement (the "Services Agreement") with Sarissa Capital Management LP ("Sarissa Capital"), pursuant to which Sarissa Capital provides a variety of strategic services to us in order to assist us in the development and execution of our acquisition strategy. The services shall be provided free of charge to us.

Innoviva Strategic Partners LLC, our wholly owned subsidiary ("Strategic Partners"), also entered into a subscription agreement and an Amended and Restated Limited Partnership Agreement (the "Partnership Agreement"), pursuant to which Strategic Partners became a limited partner of ISP Fund LP (the "Partnership"). The general partner of the Partnership ("General Partner") is an affiliate of Sarissa Capital and, pursuant to an investment management agreement, Sarissa Capital acts as the investment adviser to the Partnership. \$300.0 million was contributed to the Partnership for investing in "long" positions in the healthcare, pharmaceutical and biotechnology sectors.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Partnership Agreement provides for Sarissa Capital to receive a one percent management fee from the Partnership, payable quarterly in advance, measured based on the Net Asset Value of Strategic Partners' capital account in the Partnership. In addition, General Partner is entitled to a 10% annual performance allocation based on the Net Profits of the Partnership during the annual measurement period. The Partnership Agreement includes a lock-up period of thirty-six months after which Strategic Partners is entitled to make withdrawals from the Partnership as of such lock-up expiration date and each anniversary thereafter, subject to certain limitations.

As of December 31, 2020, we held 100% of the economic interest of Partnership. Total assets of the Partnership were \$299.3 million, of which all were attributable to equity and other long-term investments. During the year ended December 31, 2020, the Partnership incurred \$0.4 million in net investment-related expense and recorded an unrealized loss of \$0.4 million on the equity investments, which is included in changes in fair values of equity investments on the consolidated statements of income.

5. FINANCIAL INSTRUMENTS AND FAIR VALUE MEASUREMENTS

Equity Investment in Armata

On January 27, 2020, we entered into a securities purchase agreement with Armata Pharmaceuticals, Inc. ("Armata") to acquire 8,710,800 shares of Armata's common stock and warrants to purchase up to 8,710,800 additional shares of its common stock for approximately \$25.0 million in cash. Armata is a clinical stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections. The investment is to support Armata's ongoing advancement of its bacteriophage development programs including the expected first in human studies related to Armata's lead phage candidate, AP-PA02, targeting *Pseudomonas aeruginosa*, as well as AP-SA02, its phage candidate targeting *Staphylococcus Aureus*.

The investment was closed in two tranches on February 12, 2020 and March 27, 2020. Two of our board members joined Armata's board at the first closing and have remained on Armata's board ever since. As of December 31, 2020, we owned approximately 46.6% of Armata's common stock.

The investment provides Innoviva the ability to have significant influence, but not control over Armata's operations. Based on our evaluation, we determined that Armata is a VIE, but Innoviva is not the primary beneficiary of the VIE. We elected the fair value option to account for both Armata's common stock and warrants. The fair value of Armata's common stock is measured based on its closing market price. The warrants have an exercise price of \$2.87 per share, are exercisable immediately within five years from the issuance date of the warrants and include a cashless exercise option. We use the Black-Scholes-Merton pricing model to estimate the fair value of these warrants with the following input assumptions: Armata's closing market price on the valuation date, the risk-free interest rate computed based on the U.S. Treasury yield, the remaining contractual term as the expected term, and the expected stock price volatility calculated based on the historical volatility of the common stock of Armata and its peer companies.

As of December 31, 2020, the fair values of Armata's common stock and warrants were estimated at \$26.0 million and \$18.0 million, respectively. The total fair value of both financial instruments in the amount of \$44.0 million was recorded as equity and long-term investments on the consolidated balance sheets as of December 31, 2020. We recorded \$19.0 million in unrealized gain from fair value changes in our investment in Armata securities as changes in fair values of equity, net on the consolidated statements of income for the year ended December 31, 2020.

Equity Investment in Entasis

On April 12, 2020, we entered into a securities purchase agreement with Entasis Therapeutics, Inc. ("Entasis") to purchase 14,000,000 shares of Entasis common stock as well as warrants to purchase 14,000,000 additional shares of its common stock for approximately \$35.0 million in cash (the "April 2020 Entasis Agreement"). Entasis is a clinical-stage biotechnology company focused on the discovery and development of novel antibacterial products. The investment is to support Entasis's ongoing advancement of its pathogen-targeted antibacterial product candidates, which include their global Phase 3 registration trial evaluating a fixed-dose combination of sulbactam and durlobactam (SUL-DUR) against *Acinetobacter baumannii* infections.

The investment was closed in two tranches on April 22, 2020 and June 11, 2020. Innoviva has a right to designate two members to Entasis's board.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On August 27, 2020, we entered into another securities purchase agreement with Entasis (the “August 2020 Entasis Agreement”) to purchase 4,672,897 shares of Entasis common stock as well as warrants to purchase 4,672,897 additional shares of its common stock for approximately \$12.5 million in cash. As of December 31, 2020, we owned approximately 51.0% of Entasis’s common stock.

The investment provides Innoviva the ability to have significant influence, but not control, over Entasis’s operations. Based on our evaluation, we determined that Entasis is a VIE, but Innoviva is not the primary beneficiary of the VIE. We elected the fair value option to account for both Entasis’s common stock and warrants at fair value. The fair value of Entasis’s common stock is measured based on its closing market price at each balance sheet date. The warrants have an exercise price of \$2.50 per share under the April 2020 Entasis Agreement and an exercise price of \$2.675 under the August 2020 Entasis Agreement. The warrants are exercisable immediately within five years from the issuance date of the warrants and include a cashless exercise option. We use the Black-Scholes-Merton pricing model to estimate the fair value of these warrants with the following input assumptions: Entasis’s closing market price on the valuation date, the risk-free interest rate computed based on the U.S. Treasury yield, the remaining contractual term as the expected term, and the expected stock price volatility calculated based on the historical volatility of the common stock of Entasis and its peer companies.

As of December 31, 2020, the fair values of Entasis’s common stock and warrants were estimated at \$46.1 million and \$31.9 million, respectively. The total fair value of both financial instruments in the amount of \$78.0 million was recorded as equity and long-term investments on the consolidated balance sheets. We recorded \$30.5 million in unrealized gain from fair value changes in our investment in Entasis securities as changes in fair values of equity, net on the consolidated statements of income for the year ended December 31, 2020.

Equity Investment in InCarda

On October 6, 2020, TRC entered into a securities purchase agreement with InCarda Therapeutics, Inc. (“InCarda”) to purchase 20,469,432 shares of InCarda Series C preferred stock and warrants to purchase 5,117,358 additional shares of Series C preferred stock for \$15.0 million. InCarda is a privately held biopharmaceutical company focused on developing inhaled therapies for cardiovascular diseases. The investment is intended to fund the ongoing clinical development of InRhythm™ (flecainide for inhalation), the company’s lead program, for the treatment of a recent-onset episode of paroxysmal atrial fibrillation. TRC has the right to designate one member to InCarda’s board. As of December 31, 2020, TRC held 13.4% of InCarda equity ownership.

The investment does not provide TRC the ability to control or have significant influence over InCarda’s operations. Based on our evaluation, we determined that InCarda is a VIE, but TRC is not the primary beneficiary of the VIE. We have accounted for the investment in Series C preferred shares in InCarda using the measurement alternative. Under the measurement alternative, the equity investment is initially recorded at its allocated cost, but the carrying value may be adjusted through earnings upon an impairment or when there is an observable price change involving the same or a similar investment with the same issuer. The warrants are recorded at fair value and subject to remeasurement at each balance sheet date. The warrants are exercisable immediately with an exercise price of \$0.7328 per share and expire on October 6, 2021, one year from the issuance date. We use the Black-Scholes-Merton pricing model to estimate the fair value of the warrants with the following input assumptions: the exercise price of the warrants, the risk-free interest rate computed based on the U.S. Treasury yield, the remaining contractual term as the expected term, and the expected stock price volatility calculated based on the historical volatility of the common stock of its peer companies.

As of December 31, 2020, the fair value of InCarda’s warrants was estimated at \$1.1 million and recorded as equity and long-term investments on the consolidated balance sheets. We recorded \$1.1 million unrealized gains as changes in fair values of equity investments, net on the consolidated statements of income for the year ended December 31, 2020. There was no impairment or other change to the value of the Series C preferred stock of \$15.0 million as of December 31, 2020.

Summarized Financial Data

As of December 31, 2020, the total changes in fair values of our equity investments in Armata and Entasis exceeded 10% of our income before income taxes. Rule 4-08(g) of Regulation S-X, according to the SEC guidance, requires summarized financial information of these entities in an annual report if either the investment, asset or income test as set in the rule exceeds the 10% level individually or in aggregate. The summarized financial information, including the portion we do not own in these entities, is presented for Armata and Entasis, respectively, on a one quarter lag regardless of the date of our investments as follows:

Armata Pharmaceuticals, Inc.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Balance Sheet Information

(In thousands)	September 30, 2020
Current assets	\$ 17,024
Noncurrent assets	\$ 28,651
Current liabilities	\$ 7,070
Noncurrent liabilities	\$ 13,986

Income Statement Information

(In thousands)	For the nine months ended September 30, 2020
Revenue	\$ 319
Loss from operations	\$ (15,134)
Net loss	\$ (15,557)

Entasis Therapeutics Holdings Inc

Balance Sheet Information

(In thousands)	September 30, 2020
Current assets	\$ 68,398
Noncurrent assets	\$ 1,564
Current liabilities	\$ 6,862
Noncurrent liabilities	\$ 864

Income Statement Information

(In thousands)	For the six months ended September 30, 2020
Loss from operations	\$ (26,080)
Net loss	\$ (24,529)

Available-for-Sale Securities

The estimated fair value of available-for-sale securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. Available-for-sale securities are summarized below:

(In thousands)	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds ⁽¹⁾	\$ 204,808	\$ —	\$ —	\$ 204,808
Total	<u>\$ 204,808</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 204,808</u>

⁽¹⁾ Money market funds were included in cash and cash equivalents on the consolidated balance sheets.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands)	December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities ⁽¹⁾	\$ 53,799	\$ 35	\$ —	\$ 53,834
U.S. commercial paper ⁽¹⁾	18,915	—	—	18,915
Money market funds ⁽²⁾	233,992	—	—	233,992
Total	<u>\$ 306,706</u>	<u>\$ 35</u>	<u>\$ —</u>	<u>\$ 306,741</u>

⁽¹⁾ U.S. government securities and U.S. commercial paper were included in short-term marketable securities on the consolidated balance sheets.

⁽²⁾ Money market funds were presented in cash and cash equivalents on the consolidated balance sheets.

As of December 31, 2020, all investments were money market funds. There was no credit loss as of December 31, 2020.

Fair Value Measurements

Our securities are measured at fair value on a recurring basis and our debt is carried at amortized cost basis. The estimated fair values were as follows:

Types of Instruments (In thousands)	Estimated Fair Value Measurements as of December 31, 2020 Using:				Total
	Quoted Price in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs		
	Level 1	Level 2	Level 3		
Assets					
Money market funds	\$ 204,808	\$ —	\$ —		\$ 204,808
Investments held by ISP Fund LP ⁽¹⁾	299,288	—	—		299,288
Equity investment - Armata Common Stock	25,958	—	—		25,958
Equity investment - Armata Warrants	—	18,049	—		18,049
Equity investment - Entasis Common Stock	46,122	—	—		46,122
Equity investment - Entasis Warrants	—	31,882	—		31,882
Equity investment - InCarda Warrants	—	—	1,147		1,147
Total assets measured at estimated fair value	<u>\$ 576,176</u>	<u>\$ 49,931</u>	<u>\$ 1,147</u>		<u>\$ 627,254</u>
Debt					
2023 Notes	\$ —	\$ 239,779	\$ —		\$ 239,779
2025 Notes	—	206,135	—		206,135
Total fair value of debt	<u>\$ —</u>	<u>\$ 445,914</u>	<u>\$ —</u>		<u>\$ 445,914</u>

⁽¹⁾ The investments, which consisted of equity investments of \$14.5 million and money market funds of \$284.8 million, held by ISP Fund LP were subject to a 36-month lock-up period from our initial contribution date, December 11, 2020.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Types of Instruments (In thousands)	Estimated Fair Value Measurements as of December 31, 2019 Using:			Total
	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	
Assets				
U.S. government securities	\$ —	\$ 53,834	\$ —	\$ 53,834
U.S. commercial paper	—	18,915	—	18,915
Money market funds	233,992	—	—	233,992
Total assets measured at estimated fair value	\$ 233,992	\$ 72,749	\$ —	\$ 306,741
Debt				
2023 Notes	\$ —	\$ 243,394	\$ —	\$ 243,394
2025 Notes	—	208,976	—	208,976
Total fair value of debt	\$ —	\$ 452,370	\$ —	\$ 452,370

The fair values of our equity investments in Armata’s and Entasis’s common stock and those investments held by ISP Fund LP are based on the quoted prices in active markets and are classified as Level 1 financial instruments. The fair values of our marketable securities and the warrants of Armata and Entasis classified within Level 2 are based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications.

The fair value of InCarda’s warrants is classified as Level 3 financial instruments as InCarda’s securities are not publicly traded and the assumptions used in the valuation model are based on significant unobservable and observable inputs including those of publicly traded peer companies.

The fair values of our 2023 Notes and our 2025 Notes are based on recent trading prices of the respective instruments.

6. CAPITALIZED FEES PAID TO A RELATED PARTY

Capitalized fees paid to a related party, which consist of registrational and launch-related milestone fees paid to GSK, were as follows:

(In thousands)	Amortization period	December 31,	
		2020	2019
United States	2013-2030	\$ 120,000	\$ 120,000
Europe	2013-2029	60,000	60,000
Japan	2013-2029	40,000	40,000
Gross carrying value		220,000	220,000
Accumulated amortization		(94,747)	(80,924)
Net carrying value		\$ 125,253	\$ 139,076

These milestone fees are amortized over their estimated useful lives commencing upon the commercial launch of the product in their respective regions with the amortization expense recorded as a reduction in revenue from collaborative arrangements. As of December 31, 2020, the weighted average remaining amortization period was 9.1 years.

Additional information regarding these milestone fees is included in Note 3, “Collaborative Arrangements.” Amortization expense for each of the years ended December 31, 2020, 2019 and 2018 was \$13.8 million. The remaining estimated amortization expense is \$13.8 million for each of the years from 2021 to 2025 and \$56.3 million thereafter.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. STOCK-BASED COMPENSATION

Equity Incentive Plans

In May 2012, we adopted the 2012 Equity Incentive Plan (the “2012 Plan”). The 2012 Plan provides for the grant of incentive stock options, nonstatutory stock options, RSAs, RSUs and Stock Appreciation Rights to employees, non-employee directors and consultants. As of December 31, 2020, total shares remaining available for issuance under the 2012 Plan were 4,851,655.

Employee Stock Purchase Plan

Under the 2004 Employee Stock Purchase Plan (the “ESPP”), our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The ESPP provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period composed of four consecutive six-month purchase periods. The purchase periods end on either May 15 or November 15. ESPP contributions are limited to a maximum of 15% of an employee’s eligible compensation. The maximum number of shares that an employee may purchase in any purchase period is 2,500. An employee may not purchase shares with a value greater than \$25,000 in any calendar year.

As of December 31, 2020, total shares remaining available for issuance under the ESPP were 181,699.

Director Compensation Program

Our non-employee directors receive compensation for services provided as a director. Each member of our Board of Directors who is not an employee receives both cash and equity compensation for services as a director, member of a committee of the Board of Directors, lead independent director and chairman, as applicable.

Each of our independent directors receives periodic automatic grants of equity awards under a program implemented under the 2012 Plan. These grants are non-discretionary. Only our independent directors or affiliates of such directors are eligible to receive automatic grants under the 2012 Plan. Under the program, each individual who first became a non-employee director will, on the date such individual joins the Board of Directors, automatically be granted a one-time grant of RSUs covering a number of shares of our common stock calculated as \$125,000 (\$250,000 prior to the October 2017 Amendments) divided by our common stock closing share price on the date of grant as reported on The Nasdaq Global Select Market, rounded down to the nearest whole share (the “Initial RSUs”), plus a one-time grant of RSUs covering a number of shares of our common stock calculated as \$225,000 (\$250,000 prior to the October 2017 Amendments) divided by our common stock closing share price on the date of grant as reported on The Nasdaq Global Select Market, which would be pro-rated for the number of whole months remaining until the anniversary of the prior year’s stockholders’ meeting, rounded down to the nearest whole share (the “Pro Rata RSUs”). The Initial RSUs vest in two equal annual installments, while Pro Rata RSUs vest in a single installment at the sooner of the next annual stockholder meeting or the one-year grant anniversary, in each case subject to the non-employee director’s continuous service through the applicable vesting date.

Annually, upon his or her re-election to the Board of Directors at the Annual Meeting of Stockholders, each non-employee director is automatically granted an RSU covering a number of shares of our common stock calculated as \$225,000 (\$250,000 prior to the October 2017 Amendments) divided by our common stock closing share price on the date of grant as reported on The Nasdaq Global Select Market, rounded down to the nearest whole share. These RSUs will vest at the sooner of the next annual stockholder meeting or the one-year anniversary of grant, subject to the non-employee director’s continuous service through the applicable vesting date. Following the amendment to our non-employee director compensation program, both the annual RSUs and Initial RSUs described above remained unchanged with the exception that the number of shares of our common stock subject to each award has been reduced.

These RSUs will vest in full upon the director’s death, the occurrence of a change in control or, with respect to awards made after the October 2017 Amendments, the director’s disability before the director’s service terminates. Director RSUs carry dividend equivalent rights to be credited with an amount equal to all cash dividends paid on the underlying shares of common stock while unvested. Dividend equivalents are subject to the same terms and conditions, including vesting, as the RSUs to which they attach and are paid in cash upon vesting.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock-Based Compensation Expense

Stock-based compensation expense is included in the consolidated statements of income as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
General and administrative	\$ 1,698	\$ 2,056	\$ 3,233

Stock-based compensation expense included in the consolidated statements of income by award type is as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Stock options	\$ 242	\$ —	\$ 305
RSUs	1,149	1,431	1,650
RSAs	273	615	1,920
Market-based RSUs (PSUs)	—	—	(224)
Market-based RSAs (PSAs)	—	—	(464)
ESPP	34	10	46
Total stock-based compensation expense	\$ 1,698	\$ 2,056	\$ 3,233

For the year ended December 31, 2018, \$1.7 million of stock-based compensation was reversed for the forfeited market-based awards due to the separation of senior management members.

As of December 31, 2020, the unrecognized stock-based compensation cost and the estimated weighted-average amortization period were as follows:

(In thousands)	Unrecognized Compensation Cost	Weighted-Average Amortization Period (Years)
Stock options	\$ 1,328	3.4
RSUs	351	0.3
RSAs	369	2.4
Total unrecognized compensation cost	\$ 2,048	

Compensation Awards

The following table summarizes equity award activity under the 2012 Plan and prior plans and related information:

(In thousands, except per share data)	Number of outstanding options	Weighted-Average Exercise Price of Outstanding Options	Number of outstanding RSUs	Weighted-Average Fair Value per Share at Grant	Number of outstanding RSAs	Weighted-Average Fair Value per Share at Grant
Balance as of December 31, 2019	1,087	\$ 24.18	94	\$ 13.94	78	\$ 14.46
Granted	250	14.10	85	13.30	31	14.30
Exercised	(30)	12.30	—	—	—	—
Released RSUs/RSAs	—	—	(94)	13.94	(28)	13.92
Forfeited	(152)	24.43	—	—	(51)	14.56
Balance as of December 31, 2020	1,155	22.28	85	13.30	30	14.61

As of December 31, 2020, the aggregate intrinsic value of the options outstanding and options exercisable was nil. All outstanding options were exercisable. The weighted average remaining contractual term was 3.69 years.

The total intrinsic value of the options exercised was \$0.1 million, \$0.2 million, and \$0.4 million for the years ended December 31, 2020, 2019 and 2018, respectively. The total estimated fair value of options vested was not material for the year ended December 31, 2020 and 2019, and \$0.8 million for the year ended December 31, 2018, respectively.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The total estimated fair value of RSUs vested was \$1.3 million, \$1.4 million, and \$2.6 million in the years ended December 31, 2020, 2019 and 2018, respectively.

The total estimated fair value of RSAs vested was \$0.6 million, \$0.9 million, and \$7.6 million in the years ended December 31, 2020, 2019 and 2018, respectively.

Valuation Assumptions

The weighted-average assumptions used in calculating the estimated value of our stock options on the date of grant as follows:

	Year Ended December 31, 2020
Risk-free interest rate	0.4 %
Expected term (in years)	6.11
Volatility	46.9 %
Dividend yield	0 %
Weighted-average estimated fair value of stock options granted	\$ 6.28

There were no grants of stock options during the years ended December 31, 2019 and 2018.

8. DEBT

Our debt consists of:

(In thousands)	December 31,	
	2020	2019
2023 Notes	\$ 240,984	\$ 240,984
2025 Notes	192,500	192,500
Total debt	433,484	433,484
Unamortized debt discount and issuance costs	(47,967)	(56,364)
Net long-term debt	<u>\$ 385,517</u>	<u>\$ 377,120</u>

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. 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. The 2025 Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on February 15, 2018.

The 2025 Notes are convertible, based on the applicable conversion rate, into cash, shares of our common stock or a combination thereof, at our election. The initial conversion rate for the 2025 Notes is 57.9240 shares of our common stock per \$1,000 principal amount of the 2025 Notes (which is equivalent to an initial conversion price of approximately \$17.26 per share), representing a 30.0% conversion premium over the last reported sale price of the Company's common stock on August 1, 2017, which was \$13.28 per share. The conversion rate is subject to customary anti-dilution adjustments in certain circumstances. The 2025 Notes will mature on August 15, 2025, unless repurchased or converted in accordance with their terms prior to such date. Prior to February 15, 2025, the 2025 Notes will be convertible at the option of the holders only upon the occurrence of specified events and during certain periods. From, and including, February 15, 2025, until the close of business on the second scheduled trading day immediately preceding the maturity date, the 2025 Notes will be convertible at any time.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In accordance with accounting guidance for debt with conversion and other options, 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”) 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. 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 over the term of the 2025 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Our outstanding 2025 Notes balances consisted of the following:

(In thousands)	December 31,	
	2020	2019
Liability component		
Principal	\$ 192,500	\$ 192,500
Debt discount and issuance costs, net	(46,766)	(54,597)
Net carrying amount	\$ 145,734	\$ 137,903
Equity component, net	\$ 65,361	\$ 65,361

The following table sets forth total interest expense recognized related to the 2025 Notes for the years ended December 31, 2020, 2019 and 2018:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Contractual interest expense	\$ 4,813	\$ 4,813	\$ 4,799
Amortization of debt issuance costs	601	551	505
Amortization of debt discount	7,230	6,618	6,071
Total interest and amortization expense	\$ 12,644	\$ 11,982	\$ 11,375

Convertible Subordinated Notes Due 2023

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured convertible subordinated notes, which will mature on January 15, 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately negotiated capped call option transactions in connection with the issuance of the notes. The 2023 Notes bear interest at the rate of 2.125% per year that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2013.

The 2023 Notes were convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the 2023 Notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share.

In connection with the offering of the 2023 Notes, we entered into two privately negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the initial conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share, both of which are subject to adjustments consistent with the 2023 Notes. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with an initial strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. Upon settlement, we would receive from our hedge counterparty a number of shares of our common shares that would range from zero, if the stock price was below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As a result of the partial conversion by certain holders of the 2023 Notes in July 2014, and dividends declared and paid in 2014 and 2015, the conversion rate with respect to our 2023 Notes was adjusted in total to 50.5818 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents a conversion price of approximately \$19.77 per share. As a result of the conversion rate adjustments, the capped call strike price and cap price were also adjusted to \$19.77 and \$27.04, respectively.

For the year ending December 31, 2016, we retired a portion of our 2023 Notes with a face value of \$14.1 million and carrying value of \$13.9 million by way of purchase in the open market.

Debt Maturities

The aggregate scheduled maturities of our long-term debt as of December 31, 2020 are as follows:

<u>(In thousands)</u>	
<u>Years ending December 31:</u>	
2021 to 2022	\$ —
2023	240,984
2024	—
2025	192,500
Total	<u>\$ 433,484</u>

9. COMMITMENTS AND CONTINGENCIES**Operating Lease**

In 2014, our facility leases in South San Francisco, California were assigned to Theravance Biopharma, Inc. However, if Theravance Biopharma, Inc. were to default on its lease obligations, we had in substance guaranteed the lease payments for these facilities. This lease concluded in May 2020, and we have no further obligations for the lease.

In 2019, we entered into an operating lease in Burlingame, California for approximately 2,111 rentable square feet. The new lease commenced in November 2019 with a term of thirty-six calendar months.

Minimum lease payments on our corporate headquarters as of December 31, 2020 are as follows:

<u>(In thousands)</u>	
<u>Years ending December 31:</u>	
2021	\$ 123
2022	109
Thereafter	—
Total	<u>\$ 232</u>

Indemnifications and Other Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters. We have not recognized any liabilities relating to these matters as of December 31, 2020.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. INCOME TAXES

Income tax benefit (expense) consists of the following:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Current			
State	\$ (11)	\$ (26)	\$ 19
Deferred			
Federal	(60,408)	(41,567)	190,195
State	(12)	(309)	5,859
	(60,420)	(41,876)	196,054
Total income tax benefit (expense), net	\$ (60,431)	\$ (41,902)	\$ 196,073

The impacts of the differences between the expected U.S. federal statutory income tax to our income tax expense are as follows:

(In thousands)	Year Ended December 31,		
	2020	2019	2018
Expected tax at federal statutory rate	\$ 74,392	\$ 48,908	\$ 44,154
State income tax, net of federal benefit	(26)	325	(5,878)
Non-deductible executive compensation	—	—	747
Noncontrolling interest	(14,577)	(7,078)	(2,367)
Other	839	326	310
Change in valuation allowance	(197)	(579)	(233,039)
Income tax expense (benefit), net	\$ 60,431	\$ 41,902	\$ (196,073)

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

(In thousands)	As of December 31,	
	2020	2019
Deferred tax assets		
Net operating loss carryforwards	\$ 121,839	\$ 172,359
Research and development tax credit carryforwards	55,211	55,966
Other	1,100	1,412
Total deferred tax assets before valuation allowance	178,150	229,737
Valuation allowance	(63,423)	(63,620)
Total deferred tax assets	114,727	166,117
Deferred tax liabilities		
Debt issuance discount and other	(10,596)	(11,946)
Unrealized Gain on Investment	(10,372)	—
Net deferred tax assets	\$ 93,759	\$ 154,171

We record deferred tax assets if the realization of such assets is more likely than not to occur. Significant management judgment is required in determining whether a valuation allowance against the deferred tax assets is required. We have considered all available evidence, both positive and negative, such as our historical operating results and predictability of future taxable income, in making such determination. We are also required to exercise significant management's judgment in forecasting future taxable income. Specifically, we evaluate the following criteria when considering a valuation allowance:

- the history of tax net operating losses in recent years;
- predictability of operating results;

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- profitability for a sustained period of time; and
- level of profitability on a quarterly basis.

As of December 31, 2020, we recognized \$60.4 million income tax expense and reduced the deferred tax assets by the same amount based on the taxable income generated during the year.

As of December 31, 2020, we had federal net operating loss carryforwards of approximately \$0.4 billion, of which approximately \$2.0 million can be carried forward indefinitely and the remaining will expire from 2032 through 2035. We also had federal research and development tax credit carryforwards of approximately \$43.6 million, which will expire beginning 2021. We also had state net operating loss carryforwards of approximately \$650.7 million expiring in the beginning of 2029 and state research tax credits of approximately \$32.2 million, which do not expire.

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

We conducted an Internal Revenue Code of 1986, as amended, Section 382 (“Section 382”) analysis through September 30, 2020 to determine whether an ownership change had occurred since inception. The Section 382 study concluded that it is more likely than not that the Company did not experience an ownership change during the testing period. However, notwithstanding the applicable annual limitations, no portion of the net operating loss or credit carryforwards is expected to expire before becoming available to reduce federal and state income tax liabilities as a result of those identified ownership changes. If we undergo another ownership change, the utilization of the pre-ownership change net operating loss carryforwards or pre-ownership change tax attributes, such as research tax credits, to offset the post-ownership change income may be subject to an annual limitation, pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. Similar rules may apply under state tax laws.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2020 and 2019, we had no accrued interest or penalties.

Uncertain Tax Positions

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

(In thousands)	
Unrecognized tax benefits as of December 31, 2017	\$ 15,488
Gross decrease in tax portions for 2018	(75)
Unrecognized tax benefits as of December 31, 2018	15,413
Gross decrease in tax portions for 2019	(71)
Unrecognized tax benefits as of December 31, 2019	15,342
Net decrease in tax portions for 2020	(157)
Unrecognized tax benefits as of December 31, 2020	\$ 15,185

Our total unrecognized tax benefits as of December 31, 2020 were \$15.2 million. Total unrecognized tax benefits that, if recognized, would affect our effective tax rate, were \$8.0 million as of December 31, 2020.

We are subject to taxation in the U.S. and various state jurisdictions. The tax years 2004 through 2013, 2015 and forward remain open to examination by the federal and most state tax authorities due to net operating loss and overall credit carryforward positions.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. SUBSEQUENT EVENTS

On January 26, 2021, we entered into a securities purchase agreement with Armata to acquire approximately \$20 million in Armata common stock and warrants in two tranches. The first tranche consisting of approximately 1.9 million shares of common stock and warrants to purchase an equal number of shares of common stock for an aggregate purchase price of \$6.1 million was consummated simultaneously with the execution of the agreement. The second tranche consisting of approximately 4.3 million shares of common stock and warrants to purchase an equal number of shares of common stock for an aggregate purchase price of \$13.9 million will be consummated upon satisfaction of certain closing conditions, which is expected to occur in the first quarter of 2021. The investment is to support Armata's ongoing advancement of its bacteriophage development programs, including its FDA cleared first-in-human study, SWARM-*P.a.*, which is evaluating its lead phage product candidate, AP-PA02, as a potential treatment for *Pseudomonas aeruginosa* airway infections in cystic fibrosis patients. In addition, Armata expects to initiate a second clinical trial related to another product candidate, AP-SA02, a phage targeting *Staphylococcus aureus*, in patients with complicated bacteremia later this year.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Innovia, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Innoviva, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2020 and 2019, the related consolidated statements of income, comprehensive income, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated February 25, 2021 expressed an unqualified opinion.

Basis for Opinion

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

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

Critical Audit Matter

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

Determination of VIEs and Primary Beneficiaries

As described further in notes 4 and 5 to the financial statements, certain of the Company's investments have complex structures and agreements which must be evaluated for consolidation, including determining whether the investee is a variable interest entity ("VIE"). An entity is considered to be a VIE if (a) the entity cannot finance its operations without subordinated financial support from other parties, (b) the entity's at-risk equity holders lack the characteristics of a controlling financial interest, (c) the entity is structured with non-substantive voting rights, or (d) the equity holders do not have the obligation to bear potential losses or the right to receive potential gains. If an entity has at least one of these characteristics, it is considered a VIE, and is consolidated by its primary beneficiary. This accounting assessment is performed at the inception of the investment and upon the occurrence of reconsideration events, as defined in accounting principles generally accepted in the United States of America, and requires significant judgment by management. We identified this accounting assessment of VIEs as a critical audit matter.

The principal consideration for our determination that the initial accounting assessment or reconsideration accounting assessment of VIEs for the Company's investments is a critical audit matter is that they require significant judgement by management to interpret the impact of complex agreements on the VIE and primary beneficiary determinations. The assessment made by management of whether an entity's at-risk equity holders lack the characteristics of a controlling financial interest and the Company's interest in that entity qualifies as that entity's primary beneficiary is a complex and judgmental determination. Therefore, a high degree of auditor judgement, subjectivity and effort in performing procedures is required to evaluate evidence obtained related to the initial or continuous assessment of VIEs.

Our audit procedures related to consolidation and primary beneficiary assessments included the following, among others:

- We tested the effectiveness of controls related to the initial accounting assessment of the investments and the continuous reassessment for reconsideration events, as required by the accounting framework.
- We evaluated the Company's accounting analysis for all significant investments by performing procedures including, but not limited to:
 - o Obtaining an understanding of the composition and governance of the entity, its board of directors, and management to evaluate whether management's assessment of the VIE considerations are based on the facts.
 - o Reading the purchase agreements and other related documents and evaluating the structures and terms of the agreements to verify if the investments should be classified as VIEs by evaluating management's assessment of whether an entity meets the criteria of a VIE.

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- o Considering whether the Company appropriately determined the primary beneficiary by evaluating the investment arrangements of the entity to determine if the Company has the power to direct activities, and if the Company has the obligation to absorb losses of the entity or the right to receive benefits from the entity that could be significant to the VIE.
- o Evaluating whether or not the Company consolidated the balances at the appropriate amounts for those entities where the Company has determined it is the primary beneficiary.
- o Evaluating the evidence obtained in other areas of the audit to determine if there were additional reconsideration events that had not been identified by the Company, including, among others, reading board minutes and confirming the terms of certain agreements, if any.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2019.

San Francisco, California
February 25, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Innoviva, Inc.

Opinion on the Financial Statements

We have audited the consolidated statements of operations, comprehensive income, stockholders' equity (deficit), and cash flows, of Innoviva, Inc. (the "Company") for the year ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the results of the Company's operations and its cash flows the years ended December 31, 2018, in conformity with US generally accepted accounting principles.

Basis for Opinion

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor from 1996 to 2019.

San Jose, California
February 25, 2021

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of December 31, 2020, under the supervision and with the participation of our management, including our chief executive officer and chief accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance levels.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Our independent registered public accounting firm, Grant Thornton LLP, has audited our internal control over financial reporting as of December 31, 2020. Their attestation report on the audit of our internal control over financial reporting is included below.

Limitations on the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

Internal control measures have been designed and continually evaluated for our equity and other long-term investments and the related capital allocation processes for the year ended December 31, 2020. There was no other change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during the fourth fiscal quarter of the year ended December 31, 2020 which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Innoviva, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Innoviva, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated financial statements of the Company as of and for the year ended December 31, 2020, and our report dated February 25, 2021 expressed an unqualified opinion on those financial statements.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

San Francisco, California
February 25, 2021

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated by reference from our proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2020.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2020.

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

Other than with respect to the Securities Authorized for Issuance under Equity Compensation Plans below, the information required by this Item is incorporated by reference from our proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2020.

Securities Authorized for Issuance under Equity Compensation Plans

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

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options and vesting of outstanding restricted stock units and restricted stock awards</u>	<u>Weighted-average exercise price of outstanding options</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	1,239,744 ⁽¹⁾	\$ 22.28 ⁽²⁾	5,033,354 ⁽³⁾

(1) Includes 1,155,159 shares issuable upon exercise of outstanding options and 84,585 shares issuable upon vesting of outstanding RSUs and RSAs.

(2) Does not take into account outstanding restricted stock units as these awards have no exercise price.

(3) Includes 181,699 shares of common stock available under our Employee Stock Purchase Plan.

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

The information required by this Item is incorporated by reference from our proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2020.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements:

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

	<u>Page</u>
Consolidated Balance Sheets as of December 31, 2020 and 2019	44
Consolidated Statements of Income for each of the three years in the period ended December 31, 2020	45
Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2020	46
Consolidated Statements of Stockholders’ Equity for each of the three years in the period ended December 31, 2020	47
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2020	48
Notes to Consolidated Financial Statements	49
Reports of Independent Registered Public Accounting Firm	70

2. Financial Statement Schedules:

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

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

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

ITEM 16. FORM 10-K SUMMARY

None.

Exhibits

Exhibit Number	Description	Form	Incorporated by Reference	
			Exhibit	Filing Date/Period End Date
3.1	Amended and Restated Certificate of Incorporation	S-1	3.3	7/26/2004
3.2	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3.4	3/31/2007
3.3	Certificate of Ownership and Merger Merging LABA Merger Sub, Inc. with and into Theravance, Inc., as filed with the Secretary of State of the State of Delaware, effective on January 7, 2016	8-K	3.1	1/8/2016
3.4	Amended and Restated Bylaws, amended and restated as of February 8, 2017	8-K	3.1	2/9/2017
4.1	Specimen certificate representing the common stock of the registrant	10-K	4.1	12/31/2006
4.2	Indenture, dated as of January 24, 2013 by and between Theravance, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	1/25/2013
4.3	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.4)			
4.4	Indenture (including form of Note) with respect to Innoviva's 2.50% Convertible Senior Notes due 2025, dated as of August 7, 2017, between Innoviva and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	8/7/2017
4.5	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	4.9	2/19/2020
10.1	Employee Stock Purchase Plan, as amended April 27, 2010	10-Q	10.4	6/30/2010
10.2	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002	10-Q	10.1	6/30/2014
10.3	Amended and Restated Investors' Rights Agreement by and among the registrant and the parties listed therein, dated as of May 11, 2004	S-1	10.13	6/10/2004
10.4*	Strategic Alliance Agreement between the registrant and Glaxo Group Limited, dated as of March 30, 2004	10-K	10.13	12/31/2013
10.5+	Description of Cash Bonus Program, as amended	10-K	10.22	12/31/2009
10.6+	Amendment to Change in Control Severance Plan effective December 16, 2009	10-K	10.47	12/31/2009
10.7+	2009 Change in Control Severance Plan adopted December 16, 2009	10-K	10.48	12/31/2009
10.8	Second Amendment to Amended and Restated Governance Agreement among the registrant, Glaxo Group Limited, GlaxoSmithKline plc and GlaxoSmithKline LLC, dated as of November 29, 2010	8-K	10.2	11/29/2010
10.9	Amendment to Strategic Alliance Agreement, dated October 3, 2011	10-K	10.34	12/31/2011
10.10+	2012 Equity Incentive Plan, as approved by the board of directors February 8, 2012 and approved by stockholders May 16, 2012 and forms of equity award	10-Q	10.38	6/30/2012
10.11	Base Capped Call Transaction, dated January 17, 2013	8-K	10.1	1/23/2013
10.12	Additional Capped Call Transaction, dated January 18, 2013	8-K	10.2	1/23/2013
10.13	Master Agreement by and among Theravance, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014	8-K/A	10.1	3/6/2014
10.14*	Collaboration Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited, dated March 3, 2014	8-K/A	10.2	3/6/2014
10.15*	Strategic Alliance Agreement Amendment by and between Theravance, Inc. and Glaxo Group Limited, dated March 3, 2014	8-K/A	10.3	3/6/2014
10.16	Transition Services Agreement between Theravance and Theravance Biopharma, dated June 2, 2014.	8-K	10.2	6/5/2014
10.17	Tax Matters Agreement between Theravance and Theravance Biopharma, dated June 2, 2014.	8-K	10.3	6/5/2014
10.18	Employee Matters Agreement between Theravance and Theravance Biopharma, dated June 1, 2014.	8-K	10.4	6/5/2014

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Exhibit Number	Description	Form	Incorporated by Reference	
			Exhibit	Filing Date/Period End Date
10.19	Theravance Respiratory Company, LLC Limited Liability Company Agreement between Theravance and Theravance Biopharma, dated May 31, 2014.	8-K	10.5	6/5/2014
10.20	Amendment/Clarification to Transition Services Agreement between Theravance and Theravance Biopharma, dated March 2, 2015	10-Q	10.64	3/31/2015
10.21+	First Amendment to 2009 Change In Control Severance Plan (Renamed 2009 Severance Plan)	8-K	10.2	7/29/2015
10.22	Form of Notice of Performance-Based Restricted Stock Award and Restricted Stock Award Agreement under 2012 Equity Incentive Plan (director form)	10-K	10.76	2/23/2018
10.23+	Second Amendment to 2009 Severance Plan	10-Q	10.81	7/26/2018
10.24+	Offer Letter with Marianne Zhen, dated September 7, 2018	8-K	10.1	9/11/2018
10.25+	Offer Letter between Innoviva, Inc. and Pavel Raifeld, dated May 20, 2020.	8-K	10.1	5/26/2020
10.26	Strategic Advisory Agreement, dated as of December 11, 2020, by and between Sarissa Capital Management LP and Innoviva, Inc.	8-K	10.1	12/14/2020
10.27	Amended and Restated Limited Partnership Agreement of ISP Fund LP, dated as of December 11, 2020, by and among ISP Fund LP, Sarissa Capital Fund GP LP, Innoviva Strategic Partners LLC and the other parties named therein.	8-K	10.2	12/14/2020
21.1	List of Subsidiaries			
23.1	Consent of Independent Registered Public Accounting Firm			
23.2	Consent of Independent Registered Public Accounting Firm			
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K)			
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934			
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934			
32	Certifications Pursuant to 18 U.S.C. Section 1350			
101	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets as of December 31, 2020 and 2019, (ii) Consolidated Statements of Income for the years ended December 31, 2020, 2019 and 2018, (iii) Consolidated Statements of Comprehensive Income for the years ended December 31, 2020, 2019 and 2018, (iv) Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2020, 2019 and 2018, (v) Consolidated Statements of Cash Flows for years ended December 31, 2020, 2019 and 2018, and (vi) Notes to Consolidated Financial Statements.			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101)			

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

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

POWER OF ATTORNEY

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ PAVEL RAIFELD</u> Pavel Raifeld	Chief Executive Officer (Principal Executive Officer)	February 25, 2021
<u>/s/ MARIANNE ZHEN</u> Marianne Zhen	Chief Accounting Officer (Principal Financial Officer)	February 25, 2021
<u>/s/ GEORGE BICKERSTAFF, III</u> George Bickerstaff, III	Chairman of the Board	February 25, 2021
<u>/s/ ODYSSEAS KOSTAS, M.D.</u> Odysseas Kostas, M.D.	Director	February 25, 2021
<u>/s/ MARK DIPAOLO, ESQ.</u> Mark DiPaolo, Esq.	Director	February 25, 2021
<u>/s/ JULES HAIMOVITZ</u> Jules Haimovitz.	Director	February 25, 2021
<u>/s/ SARAH SCHLESINGER, M.D.</u> Sarah Schlesinger, M.D.	Director	February 25, 2021

LIST OF SUBSIDIARIES

Name	Jurisdiction	Ownership Interest	
Theravance Respiratory Company, LLC	Delaware	(1)	
Advanced Medicine East, Inc	Delaware	100	%
Pulmoquine Therapeutics, Inc.	Delaware	(2)	
Innoviva Strategic Partners LLC	Delaware	100	%
Innoviva Royalty Sub LLC	Delaware	100	%
Innoviva TRC Holdings LLC	Delaware	100	%
Innoviva Strategic Opportunities LLC	Delaware	100	%

- (1) The Company owns 15% of the economic interests in Theravance Respiratory Company, LLC ("TRC") but has the power to direct TRC's economically significant activities and the obligation to absorb losses of, or the right to receive benefits from them. Accordingly, TRC's financial results are consolidated in the Company's financial statements.
- (2) As of December 31, 2020, the Company owned 91% of the outstanding equity and 56% of the voting power in Pulmoquine Therapeutics, Inc. ("Pulmoquine"). Pulmoquine's financial results are consolidated in the Company's financial statements.
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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated February 25, 2021, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Innoviva, Inc. on Form 10-K for the year ended December 31, 2020. We consent to the incorporation by reference of said reports in the Registration Statements of Innoviva, Inc. on Forms S-8 (File No. 333- 119559, File No. 333-129669, File No. 333-150753, File No. 333-159042, File No. 333-173923, File No. 333-181763, and File No. 333-197950).

/s/ GRANT THORNTON LLP

San Francisco, California
February 25, 2021

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement on Form S-8 No 333-119559 of Theravance, Inc. pertaining to the 2004 Equity Incentive Plan and the 2004 Employee Stock Purchase Plan,
- (2) Registration Statement on Form S-8 No 333-129669 of Theravance, Inc. pertaining to the 2004 Employee Stock Purchase Plan,
- (3) Registration Statement on Form S-8 No 333-150753 of Theravance, Inc. pertaining to the 2008 New Employee Equity Incentive Plan and the 2004 Employee Stock Purchase Plan,
- (4) Registration Statement on Form S-8 No 333-159042 of Theravance, Inc. pertaining to the 2004 Employee Stock Purchase Plan,
- (5) Registration Statement on Form S-8 No 333-173923 of Theravance, Inc. pertaining to the 2004 Employee Stock Purchase Plan,
- (6) Registration Statement on Form S-8 No 333-181763 of Theravance, Inc. pertaining to the 2012 Equity Incentive Plan, and
- (7) Registration Statement on Form S-8 No 333-197950 of Theravance, Inc. pertaining to the 2012 Equity Incentive Plan, the Amended and Restated 2008 New Employee Equity Incentive Plan, the 2004 Equity Incentive Plan and the 1997 Stock Plan

of our report dated February 19, 2019, with respect to the consolidated financial statements of Innoviva, Inc. for the year ended December 31, 2018, included in this Annual Report (Form 10-K) of Innoviva, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Jose, California
February 25, 2021

**Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Pavel Raifeld, certify that:

1. I have reviewed this Annual Report on Form 10-K of Innoviva, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ PAVEL RAIFELD

Pavel Raifeld
Chief Executive Officer
(Principal Executive Officer)

**Certification of Principal Accounting Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Marianne Zhen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Innoviva, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ MARIANNE ZHEN

Marianne Zhen
Chief Accounting Officer
(Principal Financial Officer)
