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

,

2023

or

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

☐

For the transition period from to

Commission File No. 000-30319

INNOVIVA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**94-3265960**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1350 Old Bayshore Highway, Suite 400

Burlingame
,
CA **94010**

(Address of principal executive offices) (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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023 was $

731,926,690

. This calculation does not reflect a determination that persons are affiliates for any other purpose.

On February 14, 2024, there were

63,227,333

shares of the registrant's Common Stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's definitive Proxy Statement to be issued in conjunction with the registrant's 2023 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the registrant's fiscal year ended December 31, 2023, 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.
2023 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®, GIAPREZA®, XERAVA®, and XACDURO® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the Company (including the Company's growth strategy and corporate development initiatives); the timing, manner, and amount of potential capital returns to shareholders; the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; and projections of revenue, expenses and other financial items; the impact of the novel coronavirus ("COVID-19"); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy and risks discussed 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 innovative healthcare assets. We currently have three primary sets of assets: a royalty portfolio, operating assets in critical care and infectious disease, and other strategic healthcare assets.

Our royalty portfolio contains respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, "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%.

We expanded our portfolio through the acquisition of Entasis Therapeutics Holdings Inc. ("Entasis") on July 11, 2022 and the acquisition of La Jolla Pharmaceutical Company ("La Jolla") on August 22, 2022. Our commercial and marketed products include GIAPREZA® (angiotensin II), approved in the United States ("U.S.") to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (eravacycline) approved in the U.S. for the treatment of complicated intra-abdominal infections in adults. On May 23, 2023, XACDURO® (formerly known as sulbactam-durlobactam or SUL-DUR), was approved by the United States Food and Drug Administration ("FDA") and we commenced commercial sales of XACDURO® in the third quarter of 2023. Our development pipeline includes zoliflodacin, an investigational treatment for uncomplicated gonorrhea that reported positive data in a pivotal Phase 3 clinical trial on November 1, 2023. As such, we have a wholly owned robust critical care and infectious disease operating platform with a hospital focus anchored by three differentiated products with significant growth potential and a promising drug candidate.

In addition, we own other strategic healthcare assets, such as a large equity stake in Armata Pharmaceuticals, Inc., a leader in development of bacteriophages with potential use across a range of infectious and other serious diseases. We also have economic interests in other healthcare companies.

Our focus on capital allocation and shareholder value maximization has led our company to a meaningful transformation, and 2023 was a significant transition year. In 2022 our financials contained royalty revenues from TRELEGY® ELLIPTA® which was divested mid-year in an economically accretive transaction. Additionally, our acquisition and integration of operating companies further changed the structure of our financials compared to prior years. Through these changes, we believe we are well-positioned to create significant long-term shareholder value.

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, creating value through our critical care and infectious disease platform, optimizing our operations, and augmenting capital allocation. We continue to diversify our 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 Royalty Product Portfolio

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, two of which we still retain rights in. Those two are as follows:

- 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"), and,

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

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, which are being amortized over their estimated useful lives commencing upon the commercial launch of the products.

Competition

We anticipate that RELVAR®/BREO® ELLIPTA® (FF/VI) and ANORO® ELLIPTA® (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 Respiclick® (salmeterol and fluticasone propionate), a non-substitutable generic version of Advair, marketed by TEVA

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

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

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

- Incruse® Ellipta® (umeclidinium) and Arnuity® Ellipta® (fluticasone furoate) (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.

• Atectura® Breezhaler® (indacaterol in combination with mometasone) marketed by Novartis

• Trimbow® (a fixed-dose, twice daily combination of formoterol, beclomethasone and glycopyrronium) manufactured by Chiesi and indicated for use in COPD in the E.U.

• Foster (beclomethasone dipropionate in combination with formoterol fumarate) manufactured by Chiesi and indicated for use in asthma and COPD outside the U.S.

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

• Fasenra® (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. Fasenra 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

• Tezspire® (tezepelumab-ekko), 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. The FDA approved the Tezspire solution for subcutaneous injection in December 2021; it is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

In addition, several firms have developed and launched 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.

In general, these manufacturers are required to conduct a number of clinical efficacy, pharmacokinetic and device studies to demonstrate equivalence. 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 a draft guidance document covering Fluticasone Furoate/Vilanterol Trifenatate (FF/VI), the active ingredients used in RELVAR®/BREO® ELLIPTA®.

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Our Integrated Critical Care / Infectious Disease Assets

Commercial and Marketed Products

Our critical care and infectious disease portfolio was formed through the 2022 acquisitions of Entasis and La Jolla. It comprises three differentiated commercial stage products and a pipeline. The following table summarizes our commercial and marketed products:

Product	Indication	Pivotal Studies[1]	Regulatory Status
GIAPREZA® (angiotensin II)	Septic or other distributive shock[2]	321-patient, multi-national, double-blind, randomized, placebo-controlled study	FDA approval Dec 2017 European Commission approval Aug 2019 UK authorization (post-Brexit) Jan 2021
XERAVA® (eravacycline)	Complicated intra-abdominal infections[3,4,5]	446-patient, multinational, double-blind, randomized, active-controlled study 400-patient, multinational, double-blind, randomized, active-controlled study	FDA approval Aug 2018 European Commission approval Sep 2018 Singapore approval Apr 2020 UK authorization (post-Brexit) Jan 2021 China approval March 2022 Hong Kong approval Aug 2022 Taiwan approval Sept 2023
XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use	HABP/VABP caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex[6]	177-patient, active-controlled, investigator-unblinded, independent assessor-blinded, non-inferiority, phase 3 trial	FDA approval May 2023

(1) For U.S. and European approval

(2) U.S.: GIAPREZA is a vasoconstrictor to increase blood pressure in adults with septic or other distributive shock

(3) European Union: GIAPREZA is indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies

(4) U.S.: XERAVA is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections ("cIAI") in patients 18 years of age and older

(5) European Union: XERAVA is indicated for the treatment of cIAI in adults

(6) U.S.: XACDURO is a co-packaged product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, a beta lactamase inhibitor, indicated in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex.

GIAPREZA® (angiotensin II)

GIAPREZA® (angiotensin II) injection is approved by the U.S. FDA as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. GIAPREZA is approved by the European Commission ("EC") and by the Great Britain Medicines and Health Care Products Regulatory Agency ("MHRA") for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. GIAPREZA mimics the body's endogenous angiotensin II peptide, which is central to the renin-angiotensin-aldosterone system ("RAAS"), which in turn regulates blood pressure. GIAPREZA is marketed in the U.S. by La Jolla and is marketed in Europe and Great Britain by PAION Deutschland GmbH on behalf of La Jolla. PAION AG and PAION Deutschland GmbH (together and individually "PAION") filed for insolvency in Germany on October 27, 2023 and the insolvency proceedings were opened on January 1, 2024. PAION announced on December 22, 2023 that it concluded negotiations with Humanwell Healthcare Group and entered into an agreement on the sale of the essential business operations of PAION AG and PAION Deutschland GmbH with the approval of the insolvency administrator in both procedures. La Jolla did not oppose the sale and is in discussions with the acquirer regarding the continued business relationship.

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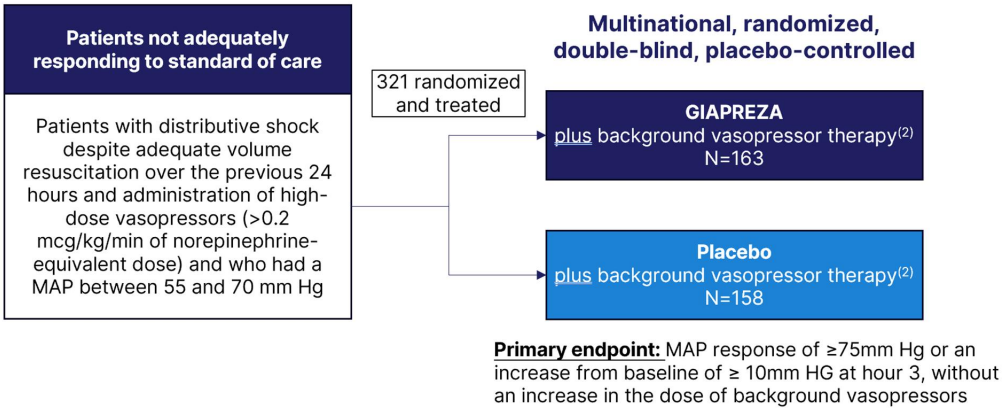
Angiotensin II for the Treatment of High-Output Shock ("ATHOS-3")

GIAPREZA was approved by the U.S. FDA, EC and MHRA based on the results of ATHOS-3, which were published in the New England Journal of Medicine in August 2017. ATHOS-3 was a multinational, randomized, double-blind, placebo-controlled study in which 321 adults with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy received either GIAPREZA or placebo, both in addition to background vasopressor therapy. The primary endpoint was mean arterial pressure ("MAP") response, defined as a MAP of 75 mm Hg or higher or an increase in MAP from baseline of at least 10 mm Hg without an increase in the dose of background vasopressors at Hour 3 (Khanna et al, New England Journal of Medicine 2017; 377:419–430).

ATHOS-3 Study Design[1]



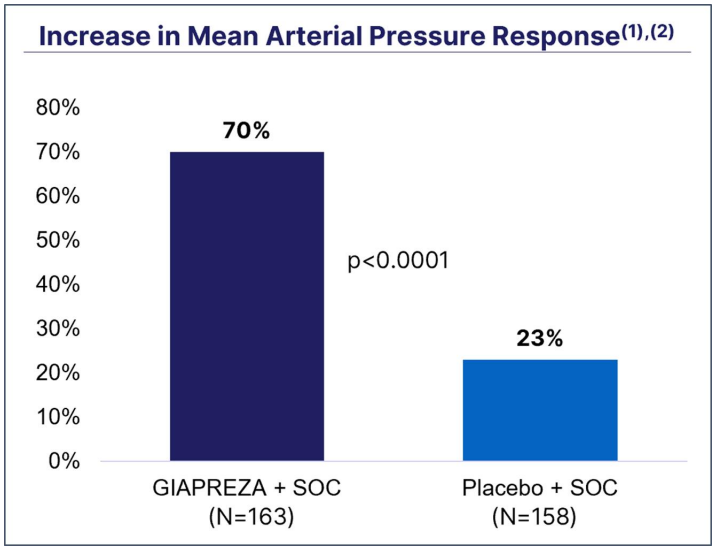
MAP=mean arterial pressure

(1) Khanna et al, New England Journal of Medicine 2017; 377:419–430

(2) Standard-of-care vasopressors included norepinephrine, epinephrine, dopamine and vasopressin

GIAPREZA significantly improved blood pressure response. Specifically, the primary endpoint was achieved by 70% of GIAPREZA-treated patients compared to 23% of placebo-treated patients (p <0.0001).

ATHOS-3 Primary Endpoint Results



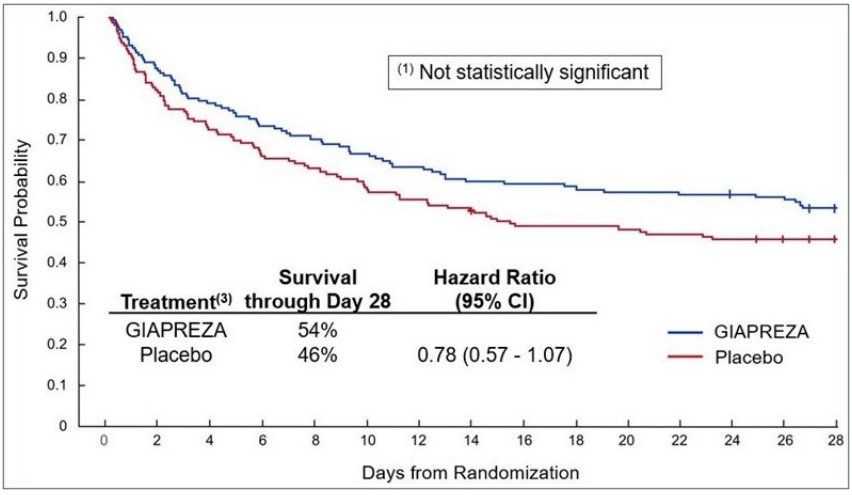
(1) Charts, graphs and tables derived from FDA prescribing information

(2) MAP response of 75 mm Hg or higher or an increase from baseline of at least 10 mm Hg at Hour 3 without an increase in the dose of background vasopressors

GIAPREZA provides the ability to rapidly achieve and adjust therapeutic response. GIAPREZA rapidly increased MAP with a median time to MAP response of approximately 5 minutes. The plasma half-life of GIAPREZA is less than 1 minute.

In addition, a positive survival trend was observed. Mortality through Day 28 was 46% on GIAPREZA and 54% on placebo (hazard ratio 0.78; 95% confidence interval 0.57–1.07).

Positive Survival Trend Observed (N=321)(1),(2)



(1) Charts, graphs and tables derived from FDA prescribing information

(2) Khanna et al, *New England Journal of Medicine 2017;* 377:419–430

(3) Patients were treated with either GIAPREZA or placebo, both in addition to background vasopressor therapy

The most common adverse reactions that were reported in greater than 10% of GIAPREZA-treated patients were thromboembolic events.

Adverse Reactions Occurring in ≥4% of Patients Treated with GIAPREZA and ≥1.5% More Often than in Placebo-treated Patients[1]

	GIAPREZA (N=163)	Placebo (N=158)
Thromboembolic events[2]	21 (12.9%)	8 (5.1%)
Deep vein thrombosis	7 (4.3%)	0 (0.0%)
Thrombocytopenia	16 (9.8%)	11 (7.0%)
Tachycardia	14 (8.6%)	9 (5.7%)
Fungal infection	10 (6.1%)	2 (1.3%)
Delirium	9 (5.5%)	1 (0.6%)
Acidosis	9 (5.5%)	1 (0.6%)
Hyperglycemia	7 (4.3%)	4 (2.5%)
Peripheral ischemia	7 (4.3%)	4 (2.5%)

(1) Charts, graphs and tables derived from FDA prescribing information

(2) Including arterial and venous thrombotic events

XERAVA® (eravacycline)

XERAVA® (eravacycline) for injection is approved by the U.S. FDA and Singapore Health Sciences Authority ("HSA") as a tetracycline class antibacterial indicated for the treatment of cIAI due to susceptible microorganisms in patients 18 years of age and older. XERAVA is approved by the EC, MHRA, and the Hong Kong Department of Health ("DoH") for the treatment of cIAI in adults. XERAVA is marketed in the U.S. by our wholly owned subsidiary, Tetraphase Pharmaceuticals, Inc. ("Tetraphase"), and is marketed in Europe and Great Britain by PAION on behalf of Tetraphase and is marketed in mainland China, Taiwan, Hong Kong, Macau, South Korea, Singapore, the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines by Everest Medicines Limited ("Everest").

cIAIs are the second most common source of severe sepsis in the ICU cIAIs are defined as consequences of perforations of the gastrointestinal tract that result in contamination of the peritoneal space.

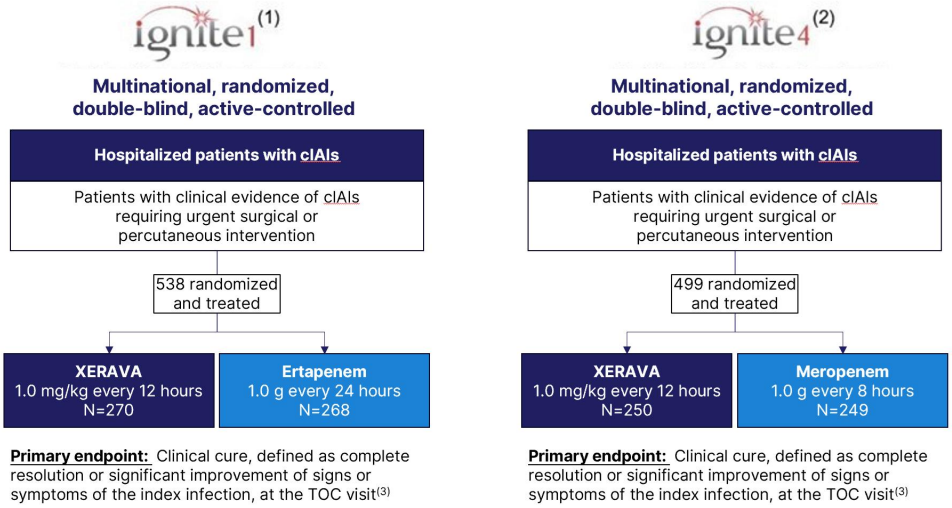
Investigating Gram-negative Infections Treated with Eravacycline ("IGNITE")

XERAVA was approved by the U.S. FDA, HSA, EC, MHRA, and DoH based on the results of IGNITE1 and IGNITE4, which were published in JAMA Surgery in March 2017 and Clinical Infectious Diseases in December 2018, respectively.

IGNITE1 was a multinational, randomized, double-blind, active-controlled study in 538 patients with clinical evidence of cIAIs requiring urgent surgical or percutaneous intervention who received either XERAVA or ertapenem. The primary endpoint was clinical cure, defined as complete resolution or significant improvement of signs or symptoms of the index infection, at the test of cure ("TOC") visit. The TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered.

IGNITE4 was a multinational, randomized, double-blind, active controlled study in 499 patients with clinical evidence of cIAIs requiring urgent surgical or percutaneous intervention who received either XERAVA or meropenem. The primary endpoint was clinical cure, defined as complete resolution or significant improvement of signs or symptoms of the index infection, at the TOC visit. The TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered.

IGNITE1 and IGNITE4 Study Design



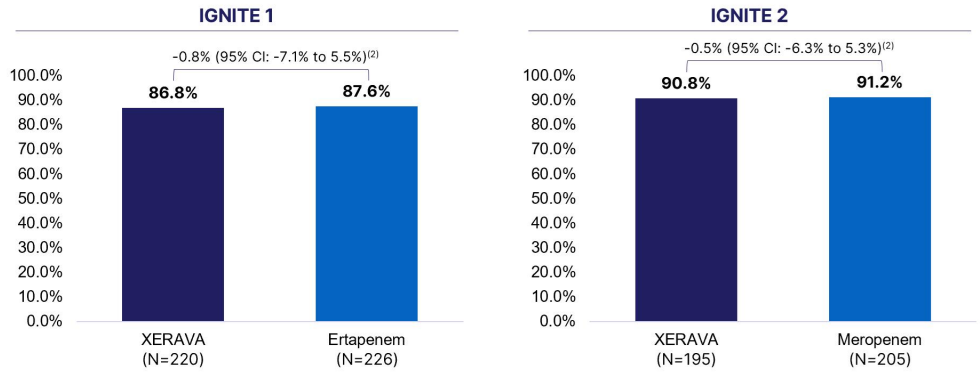
(1) Solomkin et al, *JAMA Surgery* 2017; 152(3):224-232

(2) Solomkin et al, *Clinical Infectious Diseases* 2018; 69(6):921-9

(3) TOC visit was conducted 25 to 31 calendar days after the first dose of the study drug was administered

XERAVA demonstrated statistical noninferiority in clinical cure rate in the micro-ITT population, which included all randomized subjects who had baseline bacterial pathogens that caused cIAIs and against at least one of which the investigational drug has in vitro (in a test tube) antibacterial activity (N=846).

IGNITE1 and IGNITE4 Primary Endpoint Results(1)



(1) Charts, graphs and tables derived from FDA prescribing information

(2) Noninferiority margins of 10% and 12.5% were used for IGNITE1 and IGNITE4, respectively

Clinical cure rates across patients with gram-negative, gram-positive and anaerobic pathogens, including those with resistant strains, are shown in the following tables.

Clinical Cure Rates at TOC by Selected Baseline Pathogens in the Micro-ITT Population[1]

	XERAVA (N=415) n/N1	Comparators[2] (N=431) n/N1
Enterobacteriaceae	271/314 (86.3%)	289/325 (88.9%)
Citrobacter freundii	19/22 (86.4%)	8/10 (80.0%)
Enterobacter cloacae complex	17/21 (81.0%)	23/24 (95.8%)
Escherichia coli	220/253 (87.0%)	237/266 (89.1%)
Klebsiella oxytoca	14/15 (93.3%)	16/19 (84.2%)
Klebsiella pneumoniae	37/39 (94.9%)	42/50 (84.0%)
Enterococcus faecalis	45/54 (83.3%)	47/54 (87.0%)
Enterococcus faecium	38/45 (84.4%)	48/53 (90.6%)
Staphylococcus aureus	24/24 (100.0%)	12/14 (85.7%)
Streptococcus anginosus group[3]	79/92 (85.9%)	50/59 (84.7%)
Anaerobes[4]	186/215 (86.5%)	194/214 (90.7%)

N=Number of subjects in the micro-ITT Population; N1=Number of subjects with a specific pathogen; n=Number of subjects with a clinical cure at the TOC visit

(1) Charts, graphs and tables derived from FDA prescribing information

(2) Comparators included ertapenem and meropenem for IGNITE1 and IGNITE4, respectively

(3) Includes *Streptococcus anginosus, Streptococcus constellatus, and Streptococcus intermedius*

(4) Includes *Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Parabacteroides distasonis*

The most common adverse reactions that were reported in XERAVA-treated patients in IGNITE1 and IGNITE4 were infusion site reactions.

Selected Adverse Reactions Reported in ≥1% of Patients Receiving XERAVA[1]

	XERAVA (N=520)	Comparators[2] (N=517)
Infusion site reactions[3]	40 (7.7%)	10 (1.9%)
Nausea	34 (6.5%)	3 (0.6%)
Vomiting	19 (3.7%)	13 (2.5%)
Diarrhea	12 (2.3%)	8 (1.5%)
Hypotension	7 (1.3%)	2 (0.4%)
Wound dehiscence	7 (1.3%)	1 (0.2%)

(1) Charts, graphs and tables derived from FDA prescribing information

(2) Comparators included ertapenem and meropenem for IGNITE1 and IGNITE4, respectively

(3) Infusion site reactions include: catheter/vessel puncture site pain, infusion site extravasation, infusion site hypoaesthesia, infusion/injection site phlebitis, infusion site thrombosis, injection site/vessel puncture site erythema, phlebitis, phlebitis superficial, thrombophlebitis, and vessel puncture site swelling

XACDURO

XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use (formerly known as sulbactam-durlobactam or SUL-DUR), was approved by the United States Food and Drug Administration ("FDA") on May 23, 2023, and we commenced commercial sales of XACDURO® in the third quarter of 2023. XACDURO® is a novel IV antibiotic. The product is a combination of sulbactam, a β-lactam antibiotic, and durlobactam, a novel β-lactamase inhibitor ("BLI") with broad spectrum β-lactamase coverage including Classes A, C and D, that was specifically developed for the treatment of a variety of serious infections caused by carbapenem-resistant *Acinetobacter*. We believe that XACDURO® is addressing a large unmet medical need in treating patients with serious *Acinetobacter* infections who prior to this launch have had few options for effective treatment.

Acinetobacter

Acinetobacter is a Gram-negative, opportunistic human pathogen that predominantly infects critically ill patients often resulting in severe pneumonia and bloodstream infections but also capable of infecting other body sites as well. Once thought to be mostly benign, *Acinetobacter* is now considered a global threat in the healthcare setting due in part to its ability to acquire multidrug resistance at rates not previously seen in other bacteria. In addition, *Acinetobacter* can remain viable for up to 100 days in dry conditions and easily spreads via air or water droplets, which explains why the pathogen can often be found in many locations in the intensive care unit, or ICU, including bedrails, bedside tables, monitors of mechanical ventilators, intravenous pumps, door handles, stethoscopes and many other locations. Of significant concern, one study reported greater than 98% of *Acinetobacter* isolates in an ICU from non-clinical sources, such as bedrails and door handles, were determined to be multidrug resistant.

Pneumonia and bloodstream infections caused by drug-resistant *Acinetobacter* can have mortality rates up to 50%. Antibiotic-resistance rates of Acinetobacter to current standard-of-care treatments are some of the highest reported, between 30% and 50% in the United States and greater than 90% in parts of Europe and Asia. Acinetobacter resistance to β-lactams is primarily driven by the expression of Class D β-lactamases, often in combination with Class A and/or Class C β-lactamases. There are currently no effective antibiotics specifically indicated for the treatment of multidrug-resistant *Acinetobacter* infections. Durlobactam is the first clinical-stage BLI with sufficient broad-spectrum activity against class A, C, and D β-lactamases to potentially restore the efficacy of β-lactam antibiotics against multidrug-resistant *Acinetobacter*.

Sulbactam, the β-lactam antibiotic used in XACDURO has superior microbiological potency against *Acinetobacter* compared to other β-lactam antibiotics based on *in vitro* and *in vivo* analyses. Historically, physicians used sulbactam to successfully treat *Acinetobacter* infections before development of broad β-lactamase mediated resistance rendered sulbactam on its own largely ineffective. We believe our data demonstrates that combining durlobactam with sulbactam can effectively restore the activity of sulbactam against multidrug-resistant strains of *Acinetobacter*.

Acinetobacter Treatment Trial Against Colistin ("ATTACK")

We completed ATTACK, a Phase 3 registration trial of XACDURO for the treatment of patients with carbapenem-resistant *Acinetobacter* infections, with positive top-line data announced in October 2021 and published in *The Lancet Infectious Diseases* in May 2023. ATTACK enrolled 207 patients at 95 clinical sites in 16 countries. This was a two-part trial with Part A being the randomized, comparative portion (XACDURO vs colistin) in patients with documented *Acinetobacter* hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VAPB), ventilated pneumonia (VP), or bacteremia, and Part B being an open-labeled portion including *Acinetobacter* infections resistant to, or having previously failed colistin or polymyxin B treatment. Baseline *Acinetobacter* isolates tested were greater than 95% carbapenem resistant.

XACDURO met the primary efficacy endpoint of 28-day all-cause mortality compared to colistin in the CRABC m-MITT population of Part A. XACDURO mortality was 19.0% (12/63) compared to 32.3% (20/62) in the colistin arm (treatment difference of -13.2%; 95% CI: -30.0, 3.5). Similar trends were demonstrated in 28-day and 14-day all-cause mortality favoring XACDURO across all study populations evaluated to date. A statistically significant difference in clinical cure at Test of Cure (TOC) was observed with 61.9% in the XACDURO arm compared to 40.3% in the colistin arm (95% CI 2.9-40.3). In Part B, the 28-day all-cause mortality was 17.9% (5/28) and consistent with that observed in Part A.

Safety analyses from a total of 177 patients treated with XACDURO suggested that XACDURO was generally well-tolerated with a favorable safety profile compared to colistin. XACDURO met the primary safety objective with a statistically significant lower incidence of nephrotoxicity as measured by the RIFLE classification for acute kidney injury. XACDURO nephrotoxicity was 13.2% (12/91) versus 37.6% (32/85) in the colistin arm (p = 0. 0002). Overall adverse events (AEs) in the safety population were comparable between treatment groups with 87.9% (80/91) in the XACDURO arm vs. 94.2% (81/86) in the colistin arm in Part A, 89.3% (25/28) in Part B. Drug related AEs were 12.1% (10.7% in Part B) with XACDURO compared to 30.2% with colistin. The most common non-infectious AEs (≥10%) in the XACDURO arm were diarrhea (16.5%), allergic and hypersensitivity reactions (16.5%), anemia (13.2%) and hypokalemia (12.1%) in Part A. These AEs were also >10% in the colistin arm as was acute kidney injury.

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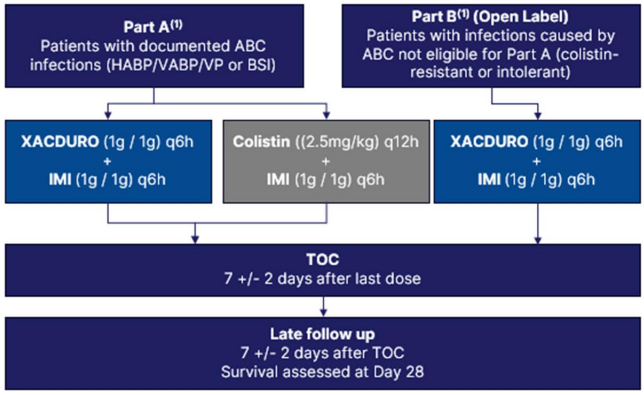
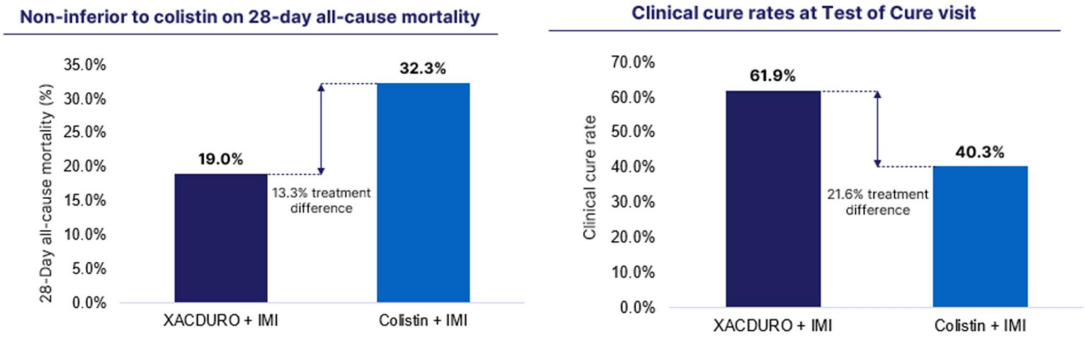
ATTACK Study Design



IMI=Imipenem; TOC=Test of cure; HABP=hospital acquired bacterial pneumonia; VABP=ventilator associated bacterial pneumonia; VP=ventilated pneumonia; BSI=blood stream infection; ABC=*Acinetobacter baumannii-calcoaceticus* complex

(1) 2-part study, Part A being the randomized, controlled portion of the study in patients with ABC HABP / VABP or bacteremia. Part B is the single-group portion of the study and includes ABC infections that are resistant to or have failed colistin or polymyxin B treatment, as detailed in the inclusion criteria. Part B is deemed as not relevant to the HABP / VABP indication

ATTACK Primary Endpoint Results(1)



IMI=Imipenem

(1) Charts, graphs and tables derived from FDA prescribing information. Kaye et al. *Lancet Infect Dis.* 2023 May 11:S1473-3099(23)00184-6

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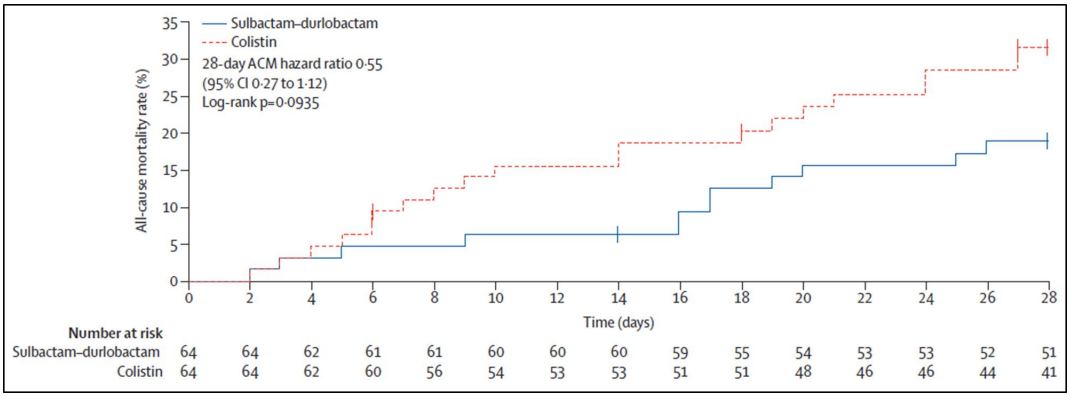
Selected Adverse Reactions Occurring at a Frequency of >5% in Trial 1[(1)]

	XACDURO (N=91)	Colistin (N=86)
Any adverse reaction	80 (88%)	81 (94%)
Liver test abnormalities[(2)]	17 (19%)	18 (21%)
Diarrhea	15 (17%)	9 (11%)
Anemia	12 (13%)	12 (14%)
Hypokalemia	11 (12%)	9 (11%)
Arrhythmia	8 (9%)	8 (9%)
Acute kidney injury	5 (6%)	31 (36%)
Thrombocytopenia	5 (6%)	3 (4%)
Constipation	5 (6%)	5 (6%)

(1) Charts, graphs and tables derived from FDA prescribing information

(2) Liver test abnormalities includes the following adverse reactions: liver function test abnormal, hepatic function abnormal, increased transaminases, ALT increased, and AST increased; Acute kidney injury includes the following adverse reactions: renal impairment, blood Cr increased, toxic nephropathy, renal failure and acute kidney injury.

All-cause mortality: Kaplan-Meier analysis of time to death by day 28[(1)]



(1) Kaye et al. *Lancet Infect Dis.* 2023 May 11:S1473-3099(23)00184-6

Competition

GIAPREZA® competes with catecholamines (primarily norepinephrine), which are available as generics and inexpensive and typically used first line to treat distributive shock, and vasopressin, including Vasostrict® (Endo International plc) and vasopressin generic drugs, which are typically used second line. In the randomized, Phase 3 study ATHOS-3, GIAPREZA® demonstrated clinical benefit in patients who were not adequately responding to available vasopressors, including catecholamines and vasopressin. GIAPREZA®'s principal competition as a treatment in patients not adequately responding to available vasopressors is the use of these same vasopressors at increased doses. If we are unable to successfully change treatment practices, the commercial prospects for GIAPREZA® will be limited, and our business may suffer.

XERAVA® competes with a number of antibiotics that are currently marketed for the treatment of cIAI and other multidrug resistant infections, including: AVYCAZ (ceftazidime and avibactam, marketed by AbbVie Inc.); MERREM IV® (meropenem, marketed by AstraZeneca PLC); PRIMAXIN® (imipenem and cilastatin, marketed by Merck & Co., Inc.); RECARBRIO™ (imipenem, cilastatin, and relebactam, marketed by Merck & Co., Inc.); TYGACIL® (tigecycline, marketed by Pfizer Inc.); VABOMERE™ (meropenem and vaborbactam, marketed by Melinta Therapeutics, Inc.); ZERBAXA® (ceftolozane and tazobactam, marketed by Merck & Co., Inc.); ZOSYN® (piperacillin and tazobactam, marketed by Pfizer Inc.); and current and future generic versions of marketed antibiotics. If we are unable to successfully change treatment practices, the commercial prospects for XERAVA® will be limited, and our business may suffer.

XACDURO® competes with a number of antibiotics that are used to treat carbapenem-resistant *Acinetobacter* infections in the absence of other products indicated for these infections, including: FETROJA® (cefiderocol, marketed by Shionogi & Co., Ltd.), UNASYN® (ampicillin and sulbactam, marketed by Pfizer Inc.), colistin (polymyxin E), and other current and future generic versions of marketed antibiotics. There are at least two additional early-stage clinical programs developing investigational therapies for multidrug-resistant *Acinetobacter* infections. If we are unable to successfully change treatment practices, the commercial prospects for XACDURO® will be limited, and our business may suffer.

Regulatory Exclusivity

GIAPREZA®, XERAVA® and XACDURO® are New Chemical Entities (“NCEs”) approved by the U.S. FDA. In the U.S., NCEs approved by the FDA are eligible for market exclusivity under the U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”), which can prevent the approval of generic versions of the NCE for 5 to 7.5 years from the date of the initial approval of the NCE. Specifically, the FDCA provides a 5-year period of marketing exclusivity within the U.S. to the applicant that gains approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application (“ANDA”) or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all of the data required for approval. However, an application may be submitted 4 years after the NDA approval of the NCE if it contains a certification of patent invalidity or non-infringement. Should the NDA holder commence litigation against the ANDA filer within 45 days of receipt of the certification notice, an automatic stay of the approval of any generic competition goes into effect until the earlier of: (i) 30 months from the receipt of the certification; or (ii) a court ruling of patent invalidity or non-infringement for the relevant patents. In the absence of a court ruling, the 30-month stay will be extended by such amount of time (if any) that is required for 7.5 years to have elapsed from the date of NDA approval of the NCE.

On February 15, 2022, La Jolla received a paragraph IV notice of certification (the “Notice Letter”) from Gland Pharma Limited (“Gland”) advising that Gland had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking approval to manufacture, use or sell a generic version of GIAPREZA® in the U.S. prior to the expiration of U.S. Patent Nos.: 9,220,745; 9,572,856; 9,867,863; 10,028,995; 10,335,451; 10,493,124; 10,500,247; 10,548,943; 11,096,983; and 11,219,662 (the “GIAPREZA® Patents”), which are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). The Notice Letter alleges that the GIAPREZA® Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Gland’s ANDA.

On March 29, 2022, La Jolla filed a complaint for patent infringement of the GIAPREZA® Patents against Gland and certain related entities in the United States District Court for the District of New Jersey in response to Gland’s ANDA filing. In accordance with the Hatch-Waxman Act, because GIAPREZA® is a new chemical entity and La Jolla filed a complaint for patent infringement within 45 days of receipt of the Notice Letter, the FDA cannot approve Gland’s ANDA any earlier than 7.5 years from the approval of the GIAPREZA® NDA unless the District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable and/or not infringed.

On February 22, 2023, La Jolla received a paragraph IV notice of certification (the “Second Notice Letter”) from Gland advising that Gland had amended its ANDA filing to include a paragraph IV certification alleging that all claims of the newly-issued and Orange Book-listed U.S. Patent No. 11,559,559 (“the ’559 Patent”), which covers GIAPREZA®, are invalid, unenforceable and/or not infringed.

On March 22, 2023, La Jolla filed a First Amended Complaint in this litigation adding Gland's marketing and distribution partners for its ANDA angiotensin II product, Fresenius Kabi USA LLC and Fresenius Kabi SwissBiosim GmbH (collectively, the "Fresenius Kabi Defendants"), as co-defendants. On April 7, 2023, La Jolla filed a Second Amended Complaint in response to the Second Notice Letter, adding claims that the manufacture, use, sale, offer for sale, or import of Gland's ANDA angiotensin II product will infringe the '559 Patent. On November 14, 2023, La Jolla filed a Third Amended Complaint adding additional infringement claims against the Fresenius Kabi Defendants. We intend to vigorously enforce our intellectual property rights relating to GIAPREZA®.

Fact discovery is set to conclude on February 29, 2024 and expert discovery will be complete by July 12, 2024. A trial date has not yet been set in this matter.

Under the Generating Antibiotic Incentives Now ("GAIN") provisions of the FDA Safety and Innovation Act ("FDASIA"), the FDA may designate a product as a qualified infectious disease product ("QIDP"). In order to receive this designation, a drug must qualify as an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections. We obtained a QIDP designation for the IV formulation of XERAVA® for cIAI in July 2013. Upon approving an application for a QIDP, the FDA will extend by an additional 5 years any non-patent marketing exclusivity period awarded, such as a 5-year exclusivity period awarded for an NCE. This extension is in addition to any pediatric exclusivity extension awarded. XERAVA® has been awarded this 5-year exclusivity under FDASIA.

Our Pipeline

The following table summarizes the status of our primary product candidate:

Product candidate / indication	Pre-clinical	Phase 1	Phase 2	Phase 3	NDA	Program status	Commercial rights	Partnerships / funding
Zoliflodacin (Oral) Uncomplicated gonorrhea						Positive Phase 3 top line data reported Nov 2023	All developed countries[1]	GARDP

(1) Global Antibiotic Research and Development Partnership ("GARDP") fully funded the Phase 3 clinical trial and pharmaceutical development activities and has commercial rights in WHO defined low-income and specified middle-income countries. We have retained commercial rights in major markets in North America, Europe and Asia-Pacific

Zoliflodacin

Zoliflodacin is a late-stage product candidate, a potential single oral dose cure for the treatment of uncomplicated gonorrhea caused by the bacterial pathogen *N. gonorrhoeae*. Gonorrhea is an area of significant medical need and zoliflodacin is the only novel single dose treatment in development that provides a potential monotherapy oral alternative to intramuscular injections of ceftriaxone for the treatment of gonorrhea, including infections caused by drug-resistant strains. Zoliflodacin targets the validated mechanism of action of the fluoroquinolone class of antibiotics but does so in a novel manner to avoid existing fluoroquinolone resistance. In November 2023, we reported positive top-line data results of a pivotal Phase 3 trial. The study demonstrated statistical non-inferiority of microbiological cure at the urogenital site when compared to treatment with intramuscular infection of ceftriaxone and oral azithromycin, a current global standard of care regimen. This trial was initiated in 2019 in collaboration with GARDP, who funded all the Phase 3 clinical trial and pharmaceutical development costs and in return received commercial rights for zoliflodacin in WHO-defined low-income and select middle-income countries. We retained commercial rights in all other countries, including the major markets in North America, Europe and Asia-Pacific.

Gonorrhea

Uncomplicated gonorrhea is an *N. gonorrhoeae* infection of the urethra, cervix, pharynx or rectum, and is more common than complicated gonorrhea, which includes spread of the infection to other tissues and potentially the bloodstream. Gonorrhea can be associated with serious complications, including pelvic inflammatory disease, ectopic pregnancy and infertility, as well as an increased risk of human immunodeficiency virus, or HIV. Despite the continued use of effective antibiotics, it remains one of the most common sexually transmitted bacterial infections in the world with an estimated 82 million people worldwide infected each year, including over 1 million people each year in the United States. The occasional absence of symptoms, more frequent in women, is thought to be one reason for sustained levels of infection. Antibiotics remain the mainstay for treating uncomplicated gonorrhea caused by *N. gonorrhoeae.*

N. gonorrhoeae is the bacterial pathogen responsible for gonorrhea and has a strong propensity for uptake of chromosomal DNA from other genera of *Neisseria* which allows the bacteria to accumulate many mutations in chromosomal genes leading to frequent resistance of antibiotics. For example, penicillin was introduced for *N. gonorrhoeae* infections in 1943, and initial resistance was reported in 1945. Fluoroquinolone antibiotics were first used to treat gonorrhea in 1949 and have been one of the most successful classes of antibiotics against *N. gonorrhoeae*, but even so resistance was identified in 1969. One member of this class, ciprofloxacin, was introduced in 1980 and resistance was identified in 1990. More recently cephalosporin antibiotics, notably cefixime, had been widely used for the treatment of gonorrhea due to their oral administration along with a favorable efficacy and safety profile, although resistance by *N. gonorrhoeae* has been reported since 2007. As widespread use of these antibiotics drove the emergence of drug-resistant *N. gonorrhoeae* strains, treatment guidelines have subsequently been amended. Ceftriaxone is currently the only CDC-recommended option for the treatment of gonorrhea and, until recently, was administered with azithromycin, a broad-spectrum antibiotic, to provide coverage against other sexually transmitted diseases that tend to occur concurrently with gonorrhea. However, rising resistance of *N. gonorrhoeae* to azithromycin recently prompted the CDC to now recommend 500mg ceftriaxone monotherapy. Ceftriaxone is administered by intramuscular injection, which can be painful and may require patient monitoring by a healthcare administrator. Although ceftriaxone remains effective in most of the U.S., in Hawaii and Massachusetts as well as in several countries, including China, Japan, Vietnam, South Korea, France and Spain, *N. gonorrhoeae* strains with resistance to azithromycin and ceftriaxone have been reported, prompting concerns that multidrug-resistant gonorrhea may become a major community health issue.

Market Opportunity

N. gonorrhoeae is an immediate global public health threat with 82.4 million cases worldwide in 2020 (WHO estimate). Cases of gonorrhea in the United States have reached an estimated 1.6 million per year. The CDC estimates that the cases of gonorrhea in the United States have been increasing at least 10% per year since 2009.

The results of a 2017-2018 survey of countries reporting decreased susceptibility, DS, or resistance, R, of *N. gonorrhoeae* to current antibiotics are reflected in the table below.

Antibiotic	Countries with DS or R
Oral ciprofloxacin	70/70 (100%)
Oral azithromycin	51/61 (84%)
Oral cefixime	24/51 (47%)
Ceftriaxone	21/68 (31%)

Historically, to reduce the risk of spreading drug-resistant *N. gonorrhoeae*, the CDC has changed treatment guidelines when resistance rates to recommended first-line treatments reach 5%. Since 2015, there has only been one recommended treatment on CDC guidelines for gonorrhea: 250mg intramuscular injection of ceftriaxone plus 1g of oral azithromycin. In 2020 the CDC once again updated its treatment guideline, now recommending a 500mg intramuscular injection of ceftriaxone for treatment of uncomplicated gonorrhea. This follows a 2019 update in the United Kingdom where recommended empirical treatment of gonorrhea is now 1 g intramuscular ceftriaxone monotherapy.

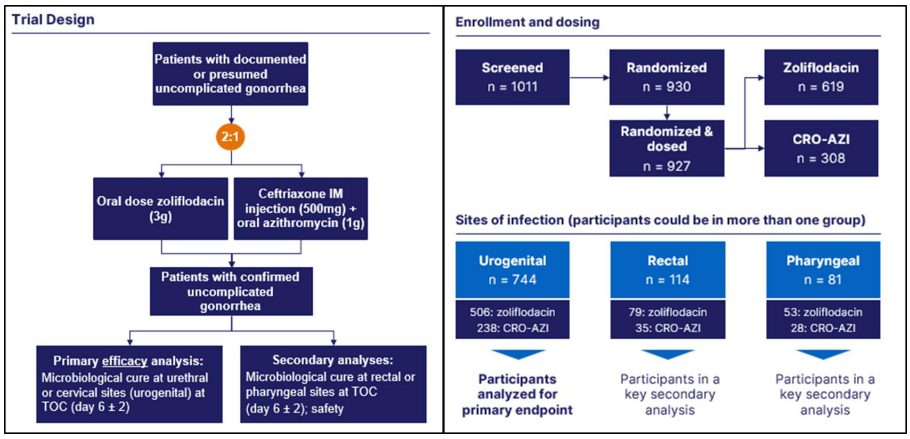
We believe that as resistance to ceftriaxone continues to grow both in the US and around the world, there is an increasing unmet medical need for drugs effective against resistant strains of *N. gonorrhoeae* and also for an oral therapy for those patients who cannot get an in-office intramuscular injection or prefer a more convenient option.

Completed Clinical Trials

Phase 3 registrational trial: We completed a global, multi-center Phase 3 registrational trial in collaboration with GARDP who conducted and funded all Phase 3 clinical trial and pharmaceutical development costs. The Phase 3 trial enrolled a total of 930 patients with uncomplicated gonorrhea, including women, adolescents, and people living with HIV, making it the largest clinical trial ever conducted for a new treatment against gonorrhea infection, with 16 trial sites in regions with a high prevalence of gonorrhea across five countries, including Belgium, the Netherlands, South Africa, Thailand, and the U.S. The trial compared a single, oral, 3g dose of zoliflodacin to a globally recognized standard of care regimen (500mg ceftriaxone IM plus 1g oral azithromycin) for the treatment of uncomplicated gonorrhea.

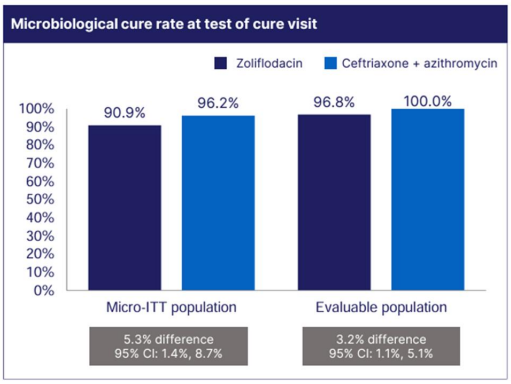
Zoliflodacin met the prespecified statistical test for non-inferiority when compared to ceftriaxone and oral azithromycin (5.31% (95%CI 1.38, 8.65%)). Non inferiority of zoliflodacin was demonstrated within the pre-specified margin of 12% and, furthermore, within the margin of 10% as specified in U.S. Food and Drug Administration guidance.

Phase 3 trial design



TOC=Test of Cure; IM=intra-muscular; CRO-AZI=ceftriaxone and azithromycin

Efficacy and safety results from Phase 3 trial[1]



	Zoliflodacin N=619 n (%)	CRO-AZI N=308 n (%)
All TEAEs	286 (46.2)	143 (46.4)
Drug-related TEAEs	117 (18.9)	76 (24.7)
SAEs	0	0
Drug-related SAEs	0	0
Withdrawals due to adverse events	0	0
TEAEs leading to death	0	0
TEAE	**Zoliflodacin**	**CRO-AZI**
Headache	61 (9.9)	14 (4.5)
Neutropenia	42 (6.8)	24 (7.8)
Leukopenia	24 (3.9)	7 (2.3)
Neutrophil count decreased	21 (3.4)	15 (4.9)
Dizziness	21 (3.4)	5 (1.6)
Nausea	16 (2.6)	12 (3.9)
Diarrhea	15 (2.4)	22 (7.1)

TEAE=Treatment emergent adverse event; CRO-AZI=ceftriaxone and azithromycin

(1) Company data, published on November 6, 2023

Phase 2 clinical proof-of-concept trial: We have completed a multi-center, randomized, open-label Phase 2 clinical trial comparing a single oral dose of 2.0g or 3.0g of zoliflodacin to 500mg intramuscular ceftriaxone for the treatment of uncomplicated gonorrhea. In this trial, 179 randomized patients received treatment and zoliflodacin was generally well tolerated, with efficacy outcomes comparable to ceftriaxone. Microbiological eradication and clinical cure in urogenital infections with a single dose of zoliflodacin, the primary endpoint of the trial, was comparable to ceftriaxone, with 100% cure rate in both the 3.0g zoliflodacin and ceftriaxone groups in the per-protocol population. The results of this clinical trial were published in *The New England Journal of Medicine* in 2018.

Phase 1 clinical trial: We evaluated zoliflodacin in two Phase 1 clinical trials studying 72 healthy volunteers in total. In one trial, we evaluated PKs and tolerability in 48 subjects and food effects in 18 subjects, and in the second trial, we evaluated absorption, distribution, metabolism and excretion in six subjects. Zoliflodacin was generally well tolerated in these trials at doses we would expect to be clinically active for treating uncomplicated gonorrhea. Administration of a high-fat meal was associated with an increase in zoliflodacin plasma concentration, suggesting that zoliflodacin could be administered with or without food.

Preclinical Data

We have generated biochemical, microbiological and *in vivo* data on zoliflodacin. The data suggest that zoliflodacin retains potent activity against contemporary clinical isolates in the U.S., Europe, China, Thailand and South Africa that are resistant to other antibiotic classes including fluroquinolones, which was expected given its novel mechanism of action. In addition, the data show significant resistance against two of the four standard antibiotics indicated for gonorrhea, ciprofloxacin, a fluoroquinolone, and azithromycin, a macrolide.

Competition

We are initially developing zoliflodacin as a single oral dose treatment for uncomplicated gonorrhea. Gonorrhea is commonly treated with 500mg intramuscular ceftriaxone, a generically available agent. Additional generic cephalosporins and fluoroquinolones are also prescribed, but not recommended as primary treatment options given current resistance rates. Gepotidacin, currently under development for a variety of infections by GlaxoSmithKline plc, is the only potentially competitive product candidate in late-stage clinical development that we are aware of that is being developed for the treatment of uncomplicated urogenital gonorrhea. A Phase 3 clinical trial (EAGLE-1) was initiated by GlaxoSmithKline in October 2019. A prior Phase 2 clinical trial revealed the emergence of resistance to gepotidacin in 2 urogenital microbiological failures following administration of a single oral dose. In an attempt to overcome this resistance, gepotidacin will be given in two oral doses in the EAGLE-1 clinical trial; a 4-tablet 3000 milligram (mg) oral dose at the study site followed by another 4-tablet 3000mg oral dose as an outpatient.

Manufacturing

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

We rely on third-party manufacturers to produce GIAPREZA®, XERAVA®, and XACDURO® and expect to continue to do so in the foreseeable future to meet our development and commercial needs. In all of our manufacturing agreements, we require that contract manufacturers produce active pharmaceutical ingredients ("APIs") and drug products in accordance with the FDA's current Good Manufacturing Practices ("cGMPs") and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to GIAPREZA®, XERAVA® and XACDURO®. The long-term commercial success of GIAPREZA®, XERAVA® and XACDURO® will depend in part on the ability of our contract manufacturers to supply cGMP-compliant API and drug product without interruption.

With respect to our product candidates, we currently rely on third-party contract manufacturers for our required raw materials, drug substance, and finished drug product for our preclinical research and clinical trials. Although we have contracts with these third parties to meet our current clinical supply needs, we do not have any current contractual relationships with these third parties for the manufacture of commercial supply of our product candidates after they are approved. As our product candidates approach potential approval by any regulatory agency, we intend to enter into agreements with third-party contract manufacturers for the commercial production of those products. We currently employ internal resources to manage our manufacturing vendor relationships and processes.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of our products and reimbursement. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulation require the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local statutes and regulations requires the expenditure of substantial time and financial resources. The failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties.

Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, or the FDCA, the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulation require the expenditure of substantial time and financial resources. Failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject us to a variety of administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters, untitled letters and similar communications;
- product seizures or recalls; or
- total or partial suspension of production or distribution, or injunctions, fines, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices or other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use, conducted in accordance with current good clinical practices, or cGCP, which are ethical and scientific quality standards and FDA requirements for conducting, recording and reporting clinical trials to assure that the rights, safety and well-being of trial participants are protected;
- preparation and submission to the FDA of an NDA;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's safety, identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical or nonclinical testing may continue even after the IND is submitted. In addition to including the results of the preclinical studies, the IND will also include one or more protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with cGCP. They must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol and any amendments must be submitted to the FDA as part of the IND, and progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. An IRB at each institution participating in the clinical trial must review and approve the protocol and any amendments before a clinical trial commences or continues at that institution, approve the information regarding the clinical trial and the informed consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, distribution, metabolism and elimination. In the case of some products for severe or life-threatening diseases, such as multidrug-resistant infections, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition.
- Phase 2. Clinical trials are initiated in a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may also be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial or trials that they believe will support approval of the new drug.

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for certain drugs and biologics. Specifically, PREA requires original NDAs, biologic license applications, or BLAs, and supplements thereto for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric assessment unless the sponsor has received a deferral or waiver.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf-life.

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to completeness review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug that, if approved, would represent a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious disease or condition may receive priority review. Requests for priority review generally must be submitted at the time of NDA submission. The FDA has agreed to specified performance goals in the review process of NDAs. Under that agreement, 90% of applications seeking approval of new molecular entities, or NMEs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for “priority review” are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that FDA receives the application. The review process may be extended by the FDA for three additional months to consider a major amendment to the application following the original submission.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing complies with cGMP requirements to assure and preserve the product’s safety, identity, strength, quality and purity. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendation.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured and tested. These pre-approval inspections may cover all facilities associated with NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. In addition, the FDA may require, as a condition of approval, risk evaluation and mitigation strategies, or REMS (which may include requirements for, restricted distribution and use), enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval.

On the basis of the FDA’s evaluation of the NDA and accompanying information, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the FDA ultimately decides that the NDA does not satisfy the criteria for approval, the FDA will issue a complete response letter to indicate that the agency will not approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Expedited Review and Approval

The FDA has various programs, including Fast Track and priority review, which are intended to expedite or simplify the process for developing and/or reviewing drugs. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the clinical development and expedite the review of drugs to treat serious diseases with the potential, based on nonclinical or clinical data, to fill an unmet medical need. Priority review is designed to give drugs that offer a significant improvement in safety or effectiveness of treatment for a serious condition an expedited review within eight months from the completed submission (six months from filing) as compared to a standard review time of twelve months from the completed submission (10 months from filing) for a standard new molecular entity NDA. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review.

The Generating Antibiotic Incentives Now Act, or GAIN Act, is intended to provide incentives for the development of new QIDPs. A new drug that is designated as a QIDP after a request by the sponsor that is made before an NDA is submitted will be eligible, if approved, for an additional five years of exclusivity beyond any period of exclusivity to which it would have previously been eligible. In addition, a QIDP will receive priority review and qualify for a Fast Track designation. QIDPs are defined as antibacterial or antifungal drugs intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen or qualifying pathogens identified by the FDA. XERAVA® and XACDURO® have been designated by the FDA as a QIDP. Zoliflodacin has also been designated as a QIDP by the FDA for the treatment of uncomplicated gonorrhea.

Patent Term Restoration and Data Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. As noted above, the Hatch-Waxman Amendments permit a patent restoration term of up to five years for a single patent for an approved product as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. We have applied for restoration of patent term for one U.S. Patent covering XERAVA® and, in the future, we may apply for restoration of patent term for other currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Data exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company using the drug entitled to data exclusivity as the reference listed drug, or RLD. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of data exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the use or conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent for other uses or conditions of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct its own preclinical and clinical studies in support of its application or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

In addition, as described above, under the GAIN Act a new drug that is designated as a QIDP is eligible for an additional five years of exclusivity to be added to certain other exclusivity periods that the application may qualify for upon approval, specifically five-year exclusivity, three-year exclusivity, and orphan exclusivity.

Pediatric Exclusivity

The Best Pharmaceuticals for Children Act provides for an additional six months of exclusivity, which is added on to patent and exclusivity periods in effect at the time the pediatric exclusivity award is granted, if a sponsor conducts clinical trials in children in response to a written request from the FDA, or a Written Request. The FDA may request studies on approved indications in separate Written Requests. The issuance of a Written Request does not require the sponsor to undertake the described studies. To date, we have not received any Written Requests.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems, including safety issues, with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA and other authorities also strictly regulate the promotional claims that may be made about prescription products. Under the FDCA the sponsor of an approved drug in the United States may not promote that drug for unapproved, or off-label, uses, although a physician may prescribe a drug for an off-label use in accordance with the practice of medicine. If we are found to have promoted off-label uses, we may be subject to significant liability, including sanctions, civil and criminal fines and penalties, and injunctions prohibiting us from engaging in specified promotional conduct.

Moreover, any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes;
- complying with certain electronic records and signature requirements; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP requirements and other laws.

Failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject us to a variety of administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters, untitled letters and similar communications;
- product seizures or recalls;
- total or partial suspension of production or distribution; or
- injunctions, fines, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and DOJ, or other governmental entities.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the EU, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under EU regulatory systems, a company may submit marketing authorization applications under the centralized, decentralized or mutual recognition procedures, or under the purely national route of approval. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases, and designated orphan medicines, and is optional for other medicines that are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency, or EMA, where it will be evaluated by the relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use, and a favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states and, by extension (after national implementing measures), in Norway, Iceland and Liechtenstein. In general, an initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure allows marketing authorization applications to be submitted simultaneously in two or more EU member states, whereas the mutual recognition procedure must be used if the product has already been authorized in at least one other EU member state. Both the decentralized and mutual recognition procedures provide for approval by one or more “concerned” member states based on an assessment of an application performed by one-member state, known as the “reference” member state.

Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state’s assessment report, each concerned member state must approve the assessment report and related materials, unless they identify a serious risk to public health. Under the mutual recognition procedure, the concerned member states have the same 90-day period to recognize the marketing authorization in the reference member state. In either case, concerns about serious risks to public health escalate through the relevant EMA scientific committees, and the disputed points may eventually result in a consensus opinion from the Committee for Medicinal Products for Human Use that is referred to the European Commission, whose decision is binding on all member states. The purely national procedure results in a marketing authorization in a single EU member state.

Following the result of a referendum in 2016, the United Kingdom left the EU on January 31, 2020, and as of January 1, 2021, the United Kingdom and EU operate separate regulatory regimes. The UK and EU announced on December 24, 2020, that they had agreed a Trade and Cooperation Agreement, or TCA, to govern their future relationship. The TCA remains provisional until formally ratified by the EU. The TCA sets out the new arrangements for trade of goods, including medicines and medical devices, which aims to ensure goods continue to flow between the EU and the UK and also has implications for product regulation and mutual recognition.

As a result of the United Kingdom’s departure from the EU, if a company wishes to sell its products in the United Kingdom, it will need to seek and maintain appropriate national marketing authorizations. The TCA does not provide for wholesale mutual recognition of the regulatory regimes and so products exported from the UK to the EU must comply with the EU’s regulatory requirements. In the pharmaceutical context, this has had a number of implications. From January 31, 2020, the UK no longer participated in EU institutions and their decision-making, including approval decisions under the centralized procedure. Moreover, the movement of finished pharmaceutical products into the EU from the UK is treated as an import from a third country. Since the TCA does not provide for mutual recognition of batch testing and release, products must be quality control tested and released in the EU. However, the UK has unilaterally waived batch testing requirements for UK imports from the EU for products placed on the market prior to January 2023. It remains to be seen how these developments will impact regulatory requirements for product candidates and products in the United Kingdom.

Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all the approved products for a particular indication. For example, in the U.S. and most major foreign markets, drugs like GIAPREZA®, XERAVA® and XACDURO® that are administered in the hospital must be purchased by the hospital and generally are not reimbursed by third-party payors. Hospitals instead are reimbursed for patient cases based on patients' diagnosed conditions under the U.S. Medicare diagnosis-related group ("DRG") system or other like systems for non-Medicare patients in the U.S. and in most major foreign markets. Adoption of new drugs that are administered in the hospital generally occurs more slowly than adoption of new drugs that are taken on an outpatient basis, which generally are paid for by third-party payors.

To secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

Health Care Laws Governing Interactions with Healthcare Providers

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict our business activities, including certain marketing practices. These laws include, without limitation, anti-kickback laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescriptions, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim for payment for items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a claim paid. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, have also been alleged to violate false claims laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal and civil statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. As with the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

In addition, we may be subject to data privacy and security regulations promulgated by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, impose certain requirements on covered entities (i.e., certain healthcare providers, health plans and healthcare clearinghouses) relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

What is more, the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the children's health insurance program (with certain exceptions) to annually report information related to certain payments or other transfers of value provided to covered recipients, including physicians, as defined by such law, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals' covered recipients and information related to certain ownership and investment interests held by physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. In addition, some state laws require drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing. Further, some state and local laws require the licensure of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Finally, in Europe, the European Union General Data Protection Regulation (2016/679) ("GDPR") contains provisions specifically directed at the processing of health information. The GDPR provides for potentially significant sanctions and contains extraterritoriality measures intended to bring non-EU companies under the regulation. In addition to the GDPR, individual countries in Europe and elsewhere in the world have enacted similar data privacy legislation. This legislation imposes increased compliance obligations and regulatory risk, including the potential for significant fines for noncompliance.

Healthcare and Other Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there were ongoing efforts to modify or repeal all or certain provisions of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under the ACA for individuals who do not maintain mandated health insurance coverage beginning in 2019. The ACA has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, the federal appellate court upheld the district court ruling that the individual mandate was unconstitutional and remanded the case back to the district court to determine whether the remaining provisions of the ACA are invalid as well. The case has been appealed to the U.S. Supreme Court where a ruling remains pending.

There were other reform initiatives under the former Trump Administration, including initiatives focused on drug pricing. For example, the Bipartisan Budget Act of 2018 contained various provisions that affect coverage and reimbursement of drugs, including an increase in the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70% starting in 2019. As another example, in 2018, President Trump and the Secretary of the HHS, released a "blueprint" to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. HHS has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. On November 20, 2020, CMS issued an interim final rule through the CMS Innovation Center whereby Medicare Part B reimbursement for "certain high-cost prescriptions drugs" would be no more than most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While some of these and other measures may require additional authorization to become effective, members of Congress and the new Biden administration have indicated that lowering prescription drug prices is a priority, but it is not yet clear what steps the Biden Administration will take or whether such steps will be successful.

There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices and address price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In 2019, the DISARM Act of 2019 was introduced in Congress as new legislation to provide financial incentives for pharmaceutical companies to develop new antibiotics. This new legislation was guided by input from the IDSA and will help to ensure that patients can access new antibiotics when they are clinically appropriate, require hospitals to establish antibiotic stewardship programs, and spur improved reporting of antibiotic use and resistance to more rapidly identify challenges and inform best practices. More recently, this legislation was reintroduced in the U.S. House of Representatives in June 2021 which aims to amend title XVIII of the Social Security Act to encourage the development and use of DISARM antimicrobial drugs, and for other purposes.

General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare, but not Medicaid, payments to providers in 2013 and will remain in effect through 2029 unless additional Congressional action is taken. There was a temporary suspension of the 2% reduction during the pandemic; that temporary suspension is scheduled to expire on March 31, 2021. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Legislation was introduced to the U.S. Senate in September 2020 which aims to reinvigorate innovation for the development of new antibiotics through a subscription contract program managed by HHS. The PASTEUR Act was introduced to provide a mechanism for funding designated 'critical need antimicrobial' drugs post FDA approval. In return, patients covered by federal insurance programs will receive these drugs at no cost. These Contracts under the PASTEUR Act could range from $750 million to $3 billion in value. It is unclear when or if the PASTEUR Act or similar incentive programs will become law. In October 2021, the PACCARB authored a letter to the Honorable Xavier Becerra, Secretary, Department of Health and Human Services recommending the passage of both DISARM and PASTEUR and the antimicrobial stewardship provisions contained within each act.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our current or future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any changes to the ACA or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

Other Laws and Regulations

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of the Nasdaq Capital Market, on which our shares of common stock are traded. We are also subject to various laws and regulations relating to safe working conditions, laboratory practices and the experimental use of animals.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our product candidates, our core technologies, and other know-how. To accomplish this we rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on trade secret protection and confidentiality agreements to protect our interests. We require our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. We file patent applications directed to our key product candidates to establish intellectual property positions. These patent applications are intended to protect new chemical entities relating to these product candidates as well as their manufacturing processes, intermediates and uses in the treatment of diseases.

The intellectual property portfolios for our commercial products, advanced product candidates, and various compounds are summarized below.

GIAPREZA®

As of February 15, 2023, the licensed intellectual property portfolio relating to GIAPREZA® included 12 issued U.S. patents, 2 pending U.S. patent applications, 9 issued foreign patents and 12 pending foreign patent applications. The issued U.S. patents, and patents that may issue from the pending U.S. patent applications, will expire between 2029 and 2034, absent any disclaimers, extensions, or adjustments of patent term. The foreign patents, and patents that may issue from the pending foreign patent applications, will expire in 2034, absent any disclaimers, extensions, or adjustments of patent term.

As of February 15, 2023, the intellectual property portfolio relating to GIAPREZA® also included 4 issued U.S. patents, 6 pending U.S. patent applications, 8 issued foreign patents and 10 pending foreign patent applications. The issued U.S. patents, and patents that may issue from the pending U.S. patent applications, will expire between 2034 and 2040, absent any disclaimers, extensions, or adjustments of patent term. The foreign patents, and patents that may issue from the pending foreign patent applications, will expire between 2034 and 2037, absent any disclaimers, extensions, or adjustments of patent term.

XERAVA®

As of February 15, 2023, we owned 2 issued U.S. patents, 1 pending U.S. patent application, 17 issued foreign patents and 4 pending foreign patent applications relating to XERAVA®. The issued U.S. patents, and the patent that may issue from the pending U.S. patent application, will have an expiration date of August 7, 2029, absent any disclaimers, extensions, or adjustments of patent term. The term of 1 of the U.S. patents has received 508 days of patent term adjustment. The foreign patents, and patents that may issue from the pending foreign applications, will likewise have an expiration date of August 7, 2029, absent any disclaimers, extensions, or adjustments of patent term.

As of February 15, 2023, we also filed applications for Supplementary Protection Certificates based on European Patent No. 2323972 covering the composition of matter and use of XERAVA®. Some applications have been granted and others are pending.

In addition, as of February 15, 2023, we also owned 2 issued U.S. patent, 1 pending U.S. patent application, 2 granted foreign patents and 9 pending foreign patent applications that relate to crystalline forms of eravacycline, any U.S. patent that may issue from the pending patent application will expire in 2037 absent any disclaimers, extensions, or adjustments of patent term. Likewise, any foreign patents that may issue from the pending foreign patent applications will expire in 2037. We also owned 7 issued U.S. patents, 1 pending U.S. patent application, 39 issued foreign patents and 12 pending foreign patent applications relating to other tetracycline-related intellectual property.

XACDURO®

As of February 15, 2023, we owned 4 issued U.S. patents, 115 issued foreign patents and 5 pending foreign patent applications (of which 1 is allowed) relating to XACDURO®. The issued U.S. patents have an expiration date of April 2, 2033 and November 17, 2035, absent any disclaimers, extensions, or adjustments of patent term. The foreign patents, and patents that may issue from the pending foreign applications, will likewise have an expiration date of April 2, 2033 and November 17, 2035, absent any disclaimers, extensions, or adjustments of patent term.

Description	United States Issued	United States Pending	United States Expiration	Foreign Issued	Foreign Pending	Foreign Expiration
GIAPREZA®	16	8	2029 - 2040	17	22	2034 - 2037
XERAVA®	4	2	2029 - 2037	19	13	2029 - 2037
XACDURO®	4	0	2033 - 2035	115	5	2033 - 2035
Other	7	1	2029 - 2037	39	12	2039 - 2037

Zoliflodacin

Our intellectual property portfolio for zoliflodacin contains patent applications directed to compositions of matter for zoliflodacin and other chemical analogs, as well as synthetic methods and methods of use and modes of treatment. As of February 15, 2023, we owned seven issued U.S. patents, 74 issued foreign patents as well as two pending foreign patent applications. The issued foreign patents are in several jurisdictions, including Australia, Brazil, Canada, China, Eurasia, the European Union, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Philippines, Singapore, South Africa, South Korea, Taiwan and the United Kingdom. Issued U.S. and foreign patents and patents issuing from pending U.S. and foreign applications have expiration dates of October 2029, January 2034 and May 2035.

Trademarks, Trade Secrets and Know-How

Our trademark portfolio currently consists of various registered trademark and service mark rights in several jurisdictions, including the United States, the European Union, Japan, Argentina, Australia, Brazil, Canada, India, Mexico, Norway, the Russian Federation, South Korea, Switzerland, Taiwan, Turkey and the United Kingdom, and pending applications in other jurisdictions. In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we routinely seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. In addition to patents and trademark protection, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees, and consultants, and invention assignment agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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 equity securities in the healthcare, pharmaceutical and biotechnology industries.

In May 2021, Strategic Partners received a distribution of $110.0 million from the Partnership to provide funding to us for a strategic repurchase of shares held by GSK. Pursuant to the letter agreement entered into between Strategic Partners, the Partnership, and Sarissa Capital Fund GP LP on May 20, 2021, Strategic Partners agreed to make additional capital contributions to the Partnership in an aggregate amount equal to the amount of the May 2021 distribution prior to March 31, 2022. A $110.0 million contribution was made during the first quarter of 2022.

Human Capital

As of December 31, 2023, we had 112 employees, all of whom were full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we consider our relations with our employees to be good. We also hire consultants and contract with third parties, as needed, to provide additional resources to support our business activities.

Our key human capital management objectives are to identify, recruit, integrate, retain and motivate our new and existing employees. We believe that our compensation and benefit programs are appropriately designed to attract and retain qualified talent. Employees receive an annual base salary and are eligible to earn performance-based cash bonuses. To create and maintain a successful work environment, we offer a comprehensive package of additional benefits that support the physical and mental health and wellness of all of our employees and their families and flexible working arrangements. Additionally, we grant equity awards in order to allow employees to share in the performance of the Company. The Chief Executive Officer regularly updates our board of directors and our committees on the operation and status of these human capital trends and activities.

Diversity, Equity and Inclusion

We have created an environment that fosters individual development while maintaining consistency in our corporate values and code of conduct. We offer seminars from external resources on diversity, equity and inclusion, or DEI, best practices and promote the fair treatment and full participation of all people in our workplace.

Health, Safety and Wellness

We strive to provide pay, benefits and other employee services that are competitive to market in the life sciences industry and create incentives to attract and retain employees. Our compensation package includes market-competitive pay, stock options and restrictive stock units, bonuses, employee spot awards, health care and retirement benefits, paid time off and family leave. We utilize third party consultants to review and update our compensation practices annually. We are also committed to the continued development of our people, providing opportunities for employees to further their career development through internal training and education programs and third party online training programs.

Environmental, Social and Governance

The management team and Board of Directors are keenly aware of the importance of environmental, social and governance issues, and the Company's need to conduct business with high standards. Our mission as an organization is to be patient-centric and develop innovative treatments to find solutions for patients suffering from rare and underserved diseases.

We collectively believe that pursuing an environmental, social and governance agenda serves the interests of all of our stakeholders, which includes our stockholders. Our employees, partners, and investors expect us to honor our values and take action to promote a more equitable and sustainable world for future generations.

As we further build our organization behind our portfolio of royalties and innovative healthcare assets, we intend to strive to understand the perspectives of the diverse clients and communities we will serve, and as such, we are intensifying our efforts to drive diversity and inclusion and a culture of belonging throughout our organization. We will strive to comply with all applicable environmental laws, regulations and policies concerning environmental protection in all our business activities and in the selection of partners we choose to work with. We are committed to strengthening our local community by contributing through volunteerism and will continue, as we have been doing, to provide donations to parties we believe will support our goal of improving patient health and well-being. We are also committed to good corporate governance. All of our employees, officers and directors must conduct themselves according to the language and spirit of our Code of Conduct, and our Board of Directors is dedicated to providing effective corporate oversight including through oversight committees such as the Nominating and Governance Committee, the Audit Committee and the Compensation Committee. As our Company grows, we will continue to integrate policies and programs that further foster this effort.

Information about our Executive Officers

The following table sets forth the name, age, and position of each of our executive officers as of February 29, 2024:

Name	Age	Positions Held
Pavel Raifeld	40	Chief Executive Officer
Stephen Basso	58	Chief Financial Officer
Marianne Zhen	55	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 LP. 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.

Stephen Basso was appointed Chief Financial Officer of the Company in August 2023. Prior to joining Innoviva, Mr. Basso served as the Chief Financial Officer and Chief Operating Officer at Cybrexa Therapeutics and has held a variety of financial leadership positions at Inozyme Pharma, Alexion Pharmaceuticals and Pfizer. He received a BS in business from Providence College and an MBA from Boston College.

Marianne Zhen, CPA, was appointed Chief Accounting Officer in July 2018. Prior to joining Innoviva in October 2014, 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. Previously, Ms. Zhen served as a member of the board of directors of CalCPA Peninsula Silicon Valley Chapter. 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 (AICPA) and a member of the California Society of Certified Public Accountants (CalCPA).

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 through January 24, 2023, 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® 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 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 and development of the products developed under the GSK Agreements. If GSK does not devote sufficient resources to the commercialization and development of these products, is unsuccessful in its efforts, or chooses to reprioritize its commercial programs, our business would be materially harmed.

- 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.

- 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.

- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of that product candidate.

- We rely on collaborations with third parties for the development of both our product and commercial candidates, and we may seek additional collaborations in the future. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product or commercial candidates.

- Even if any of our product candidates receives marketing approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- Our operations could be disrupted by failure of our information systems or cyber-attacks.

- If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

- Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

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® and ANORO® 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 but not limited to 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 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 owned by GSK, 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®, and ANORO® 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 have brought to market generic forms of the ICS/LABA drug Advair® since certain patents covering the Advair® delivery device expired in 2016. In general, these manufactures are required to conduct a 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®. 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®, 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®, and ANORO® ELLIPTA® and may continue to adversely affect them in the future. These organizations, together with governments, have increasingly imposed utilization management tools favoring the use of generic products. As these practices expand, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products. 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, presidential administrations and the U.S. Congress have taken actions in an effort to modify or replace PPACA and to implement or pass other reforms to the healthcare system, including proposed legislation related to the pricing of pharmaceuticals. 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.

A portion of our current revenues are from royalties derived from sales of our respiratory products partnered with GSK, RELVAR®/BREO® ELLIPTA® and ANORO® 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, in part, 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® and ANORO® 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® and ANORO® ELLIPTA®. GSK has launched RELVAR®/BREO® ELLIPTA® and ANORO® 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® and ANORO® 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® and ANORO® 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. 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 to eventually compete directly against sales of RELVAR®/BREO® ELLIPTA®. 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 the FDA stated that treating asthma with LABAs in combination with ICS did not result in significantly more serious asthma-related side effects than treatment with 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® or ANORO® 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® and ANORO® 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.

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 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. 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 December 31, 2023 and concluded that it is more likely than not that the Company did not experience an ownership change during the testing period. 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. 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. 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® and ANORO® 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 children ages 12-17, 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.

Pharmaceutical research and development are very costly and highly uncertain; we may not succeed in developing, licensing, or acquiring commercially successful products.

There are many difficulties and uncertainties inherent in pharmaceutical research and development, the introduction of new products, and business development activities to enhance our product pipeline.

There is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including in later stages after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payer reimbursement or coverage, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of new or better competitive products, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delays, uncertainties, unpredictability, and inconsistencies in drug approval processes across markets and agencies can result in delays in product launches, lost market opportunity, potential impairment of inventories, and other negative impacts. In addition, it can be very difficult to predict revenue growth rates of or variability in demand for new products and indications.

We cannot state with certainty when or whether our products now under development will be approved or launched; whether, if initially granted, such approval will be maintained; whether we will be able to develop, license, or otherwise acquire additional product candidates or products; or whether our products, once launched, will be commercially successful.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

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, 2023, we had $453.5 million in total debt outstanding, comprised primarily of $192.5 million in principal outstanding under our convertible senior notes due 2025 (the "2025 Notes") and $261.0 million in principal outstanding under our convertible notes due 2028 (the "2028 Notes") (the 2025 Notes and 2028 Notes, hereinafter, the "Notes"). The Notes are unsecured debt and, with the exception of the 2028 Notes, 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. 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.

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in 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.

To continue to commercialize our products, and advance the research, development, and commercialization of additional modalities, indications, and product candidates, we have expanded, and may need to further expand, our workforce. Our failure to compete effectively for talent could negatively affect sales of our current and any future approved products, and could result in material financial, legal, commercial, or reputational harm to our business.

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

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

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

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

Our success in preclinical studies or clinical trials may not be indicative of results in current or future clinical trials.

Our success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Certain product candidates may fail to show the necessary safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for drugs and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections because of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of that product candidate.

We, or our potential collaborators, may not commercialize, market, promote, or sell any product candidate without obtaining marketing approval from the FDA, the EMA or other comparable regulatory authority, and we may never receive such approvals. Even if our product candidates appear sufficiently effective and/or safe in patients in well-controlled clinical trials, it is impossible to predict if or when these product candidates will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events prior to, during, or because of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including but not limited to:

- the FDA, the EMA or other comparable regulatory authority may change from the views they have expressed to us as to the design, implementation, and/or interpretation of our clinical trials;
- the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- clinical trials of product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may not be able to complete our clinical trials in a timely manner, if at all, for example because the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate, or we may fail to recruit suitable patients to participate in a trial;
- we may fail to comply with regulatory requirements applicable to them, to the FDA's or other comparable regulatory authority's, satisfaction;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA, the EMA or other comparable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with whom we enter into agreements for clinical and commercial supplies;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- our product candidates, once exposed to greater numbers of patients, may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials or cause regulatory authorities to refuse to approve our product candidates or approve them only with significant restrictions on distribution or use;

- even if our clinical trials are successful, the FDA, the EMA or other comparable regulatory authorities may determine that the overall risk-benefit profiles of our product candidates are insufficient to support marketing authorization; and

- the approval policies or regulations of the FDA, the EMA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of those product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, such as black box warnings or a REMS program;

- be subject to additional post-marketing testing requirements; or

- be required to remove the product from the market after obtaining marketing approval.

Our product development costs may also increase if we experience delays in testing and we may be required to obtain additional funds to complete clinical trials. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of a product candidate.

If we are not successful in discovering, developing, and commercializing additional product candidates, our ability to expand and achieve our strategic objectives would be impaired.

We have chosen to devote a substantial amount of our effort on the continued clinical testing and potential regulatory approval of our product candidates. However, an element of our strategy may include the development of novel product candidates in other therapeutic areas. Our efforts to identify and develop product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including but not limited to the following:

- the research methodology used may not be successful in identifying potential product candidates;

- competitors may develop alternatives that render our product candidates obsolete or less attractive;

- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;

- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;

- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and

- the FDA, the EMA or other regulatory authorities may not approve or agree with the intended use of a new product candidate.

If we fail to develop and successfully generate revenue from other current and future product candidates, our future prospects may be harmed, and we will be more vulnerable to any problems that we or potential collaborators may encounter in developing and commercializing our current product candidates.

If we or our collaborators experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate, continue or complete clinical trials of our product candidates that we develop if we and our collaborators are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other comparable regulatory authority. We have limited experience enrolling patients in our clinical trials and cannot predict how successful we will be in enrolling patients in future clinical trials.

For instance, patients involved in our clinical trials are often in the hospital setting and the decision to participate can be made by the caregiver or doctor. Accordingly, seeking consent for patient participation may become difficult when the family and/or the patient may not be available to consider participation in a clinical trial and the providers/investigators seeking the consent often have no established relationship with the family or patient. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. If we are not successful at enrolling patients in one clinical trial, it may affect when we are able to initiate the next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. Patient enrollment is affected by other factors including but not limited to:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity and availability of clinical trial sites for prospective patients;
- the eligibility criteria for participation in the clinical trial;
- the design of the clinical trial;
- the perceived risks and benefits of the product candidate under study;
- our ability to recruit clinical trial investigators with appropriate experience;
- the availability of drugs approved to treat the diseases under study;
- the patient referral practices of physicians;
- our ability to obtain and maintain patient consents;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- the impact of public health epidemics, such as the COVID-19 pandemic.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would reduce the capital we have available to support current and future product candidates and may result in the need to raise additional capital earlier than planned and could cause the value of our common stock to decline and limit our ability to obtain additional financing.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts (generally referred to as adverse events), to their doctor. We are required to report adverse events to the FDA and other regulatory authorities. Often, it is not possible to determine whether the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm or refute these observations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates or any future product candidates, have side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which could harm our business, prospects, operating results and financial condition.

Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may significantly harm our business, financial condition and prospects.

Additionally, if any of our product candidates receive marketing approval, regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or the adoption of a REMS program to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners, and/or significant restrictions on distribution or use of the drug. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label or impose distribution or use restrictions;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials, including one or more post-market studies;
- we could be sued and held liable for harm caused to patients;
- we may be required to implement a REMS, including the creation of a medication guide outlining the risks of such side effects for distribution to patients, and/or other elements to assure safe use;
- we may need to conduct a recall; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

Interim “top-line” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may announce interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our operations could be disrupted by failure of our information systems or cyber-attacks.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades, or if we are subject to cyber-attacks. Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our employees, in digital form. Data maintained in digital form is subject to risk of cyber-attacks, which are increasing in frequency and sophistication. Cyber-attacks could include the deployment of harmful malware, viruses, worms, and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

The Company and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent, platforms, which pose difficulties in maintaining data integrity across systems. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional or improper dissemination or destruction of confidential information stored in the Company's systems.

Additionally, the California Consumer Privacy Act ("CCPA") 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.

Any breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to the Company and could have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Increased scrutiny of our environmental, social or governance responsibilities will likely result in additional costs and risks and may adversely impact our reputation, employee retention and willingness of customers and suppliers to do business with us.

There is an increasing focus from certain customers, consumers, employees and other stakeholders concerning environmental, social and governance ("ESG") matters, including corporate citizenship and sustainability. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, and customers and suppliers may be unwilling to do business with us.

The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. The disclosure frameworks we choose to align with, if any, may change from time-to-time and may result in a lack of consistent or meaningful comparative data from period to period. Ensuring there are systems and processes in place to comply with various ESG tracking and reporting obligations will require management time and expense. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals.

If we fail to adopt ESG standards or practices as quickly as stakeholders desire, fail, or be perceived to fail, in our achievement of such initiatives or goals, or fail in fully and accurately reporting our progress on such initiatives and goals, our reputation, business, financial performance and growth may be adversely impacted. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct the clinical trials for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with applicable regulatory requirements.

We have engaged contract research organizations, or CROs, to conduct our ongoing and planned clinical trials. We also expect to engage CROs for any of our other product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or ICH.

We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on government-sponsored, publicly accessible databases, such as ClinicalTrials.gov, within specified timeframes. Failure to do so by us or by third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the results of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or regulatory noncompliance on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, resulting in additional losses and depriving us of potential product revenue.

We rely on collaborations with third parties for the development of both our product and commercial candidates, and we may seek additional collaborations in the future. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product or commercial candidates.

We have limited capabilities for drug development, and our product development programs and the commercialization of our product candidates will require substantial additional cash to fund expenses. As a result of these factors, we are, and expect to continue to be, dependent on collaborations relating to the development of our existing and future product candidates. We have had and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. In addition, we may seek third-party collaborators for the development and commercialization of our product candidates, particularly for the commercialization of our product candidates outside the United States. Likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies and we may face significant competition in seeking appropriate collaborators. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future product candidates could be delayed, the commercial potential of our products could change, and our costs of development and commercialization could increase. If we enter into any future collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Our collaborations and any future collaborations we might enter into may pose a number of risks, including but not limited to:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or contractually obligated;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may be subject to geo-political actions, natural disasters or other occurrences, including public health epidemics such as the COVID-19 pandemic;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates; and

- collaborators' decisions may limit the availability of the product supplies required for development, clinical and commercial activities.

Collaboration agreements may not lead to development or successful commercialization of product or commercial candidates in the most efficient manner or at all. If a present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

Our reliance on third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities to produce clinical or commercial supplies of the product candidates that we are developing or evaluating. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and approved products, if any, to third parties.

To conduct clinical trials of our product candidates, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. If our manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed, or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

Even if we can establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including but not limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- supply chain disruptions due to geo-political actions, natural disasters or public healthy crises, including epidemics such as the COVID-19 pandemic.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

We may not be able to win government or non-profit contracts or grants to fund our product development activities.

Historically, we have relied in part on funding from contracts or grants from government agencies and non-profit entities and it is part of our strategy to continue to do so. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded, and the size of the contracts or grants to each awardee. Even if we can satisfy the award requirements, there is no guarantee that we will be selected to receive any contract or grant. If we are not successful in achieving this form of funding for our clinical trials, we will need to seek alternative means of funding which may not be available to the same extent, if at all.

Our reliance on government funding for certain of our programs adds uncertainty to our research, development and commercialization efforts with respect to those programs and may impose requirements that increase the costs of the research, development and commercialization of product candidates developed under those government-funded programs.

Aspects of certain of our development programs are currently being supported, in part, with funding from the NIH, NIAID, CARB-X and the DOD. Contracts and grants awarded by the U.S. government, its agencies and its partners, including our awards from the NIH, NIAID, CARB-X, and the DOD, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason at all;
- provide grant support to potential competitor programs;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government awards;

- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- adhering to stewardship principles imposed by CARB-X as a condition of the award;
- public disclosures of certain award information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and termination of our contracts.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance on our contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, such product candidate may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA, the EMA or other comparable regulatory agencies and can initiate commercialization of a product candidate we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- the potential and perceived advantages and disadvantages of the product candidates, including cost and clinical benefit relative to alternative treatments;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- acceptance by physicians, patients, operators of hospitals, including in-hospital formularies, and treatment facilities and parties responsible for coverage and reimbursement of the product;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the ability to manufacture our product in sufficient quantities and yields;
- the strength and effectiveness of marketing and distribution support;
- the prevalence and severity of any side effects;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling or an approved REMS;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the approval of other new products for the same indications;
- the timing of market introduction of the approved product as well as competitive products;

- the emergence of bacterial resistance to the product; and

- the rate at which resistance to other drugs in the target infections grow.

Any failure by any of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success could have a material adverse effect on our business prospects.

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition from major multi-national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to our current and future product candidates. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of drug-resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold or less costly than our product candidates, which could render our product candidates non-competitive and obsolete.

If our competitors obtain marketing approval from the FDA, the EMA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market.

Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the U.S., the FDA has issued several "interchangeability" designations for biosimilar products, and is expected to continue doing so in the future. These designations could – subject to state law requirements – enable pharmacies to substitute biosimilars for innovator biological products.

Many of such our competitors have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do as an organization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA, the EMA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or the EMA, or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs.

Counterfeit versions of our products could harm our patients and have a negative impact on our revenues, earnings, reputation and business.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Third parties may illegally distribute and sell counterfeit versions of our products. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured - often in unregulated, unlicensed, uninspected and unsanitary sites - as well as the lack of regulation of their contents.

The industry's failure to mitigate the threat of counterfeit medicines could adversely impact our business and reputation by impacting patient confidence in our authentic products, potentially resulting in lost sales, product recalls, and an increased threat of litigation. In addition, diversion of our products from their authorized market into other channels may result in reduced revenues and negatively affect our profitability.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we or our collaborators commercialize will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health care programs (such as Medicare and Medicaid), government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration.

A primary trend in the United States healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand, or the price of, any drug for which we obtain marketing approval for. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any drugs that we may develop.

We currently hold product liability insurance coverage in an amount that may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

There are a variety of risks associated with marketing our product candidates internationally, which could affect our business.

We or our collaborators may seek regulatory approval for our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including but not limited to:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- reduced level of reimbursement, pricing and insurance regimes compared to the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, fires, and public health epidemics, such as the COVID-19 pandemic.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Risks Related to Managing Our Growth

We have pursued and may continue to pursue acquisitions. Acquisitions could be difficult to integrate, divert the attention of key personnel, disrupt our business, dilute stockholder value and impair our financial results.

As part of our business strategy, we have pursued and intend to continue to pursue acquisitions of complementary businesses, products, services or technologies that we believe could accelerate our ability to compete in our existing markets or allow us to enter new markets. Any of these transactions could be material to our financial condition and results of operations. If we fail to properly evaluate or integrate acquisitions, we may not achieve the anticipated benefits of any such acquisitions, and we may incur costs in excess of what we anticipate. The failure to successfully evaluate and execute acquisitions or otherwise adequately address these risks could materially harm our business and financial results.

Acquisitions also frequently result in the recording of goodwill and other intangible assets which are subject to potential impairments which could harm our financial results. As a result, if we fail to properly evaluate acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, and we may incur costs in excess of what we anticipate. The failure to successfully evaluate and execute acquisitions or investments or otherwise adequately address these risks could materially harm our business and financial results.

Failure to realize the anticipated benefits from our acquisition of Entasis and La Jolla may affect our future results of operations and financial operations.

In connection with our acquisition of Entasis and La Jolla, we have integrated the research and development, commercial operations and personnel into our existing infrastructure. If there are unexpected difficulties in our integration of these acquired businesses, the anticipated benefits of the transaction may not be realized or may take longer to realize than expected. The anticipated benefits of the acquisition could be materially reduced by a number of factors, including but not limited to the following:

- the future revenue and gross margins of the acquired products may be materially different from those we originally anticipated;
- we could incur material unanticipated expenses;
- claims or lawsuits may arise from the acquisition transaction or from their previous business operations;
- we may experience difficulties in implementing effective internal controls over financial reporting as part of our integration actions; and
- potential growth, expected financial results, perceived synergies and anticipated opportunities may not be realized through the ongoing integration actions.

The occurrence of any or all of these events may have an adverse effect on our business and results of operations.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including challenges associated with integrating new personnel;
- the diversion of our management’s attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business.

The patent application and prosecution process are expensive and time-consuming. We, our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with our best interests. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised, and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. For example, European patent law currently restricts the patentability of methods of treatment of the human body more than United States law does. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, ex-parte reexamination, or inter partes review proceedings in the USPTO or similar proceedings elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate, a patent being held unenforceable, and/or in one or more or in patent claims being narrowed or invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection of our technology and products.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest filing date of a non-provisional application to which the patent claims priority. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our candidates might expire before or shortly after our candidates are commercialized. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union, as discussed above. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could materially harm our business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe our issued patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, trademarks, copyrights or other intellectual property. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable or that one or more claims of a patent are invalid, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the basis that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive because of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in several areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties prior to beginning research or disclosing proprietary information. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements.

Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale, distribution, import, export, and reporting of safety and other post-market information, are subject to comprehensive regulation by the FDA, the EMA and other foreign regulatory agencies. Failure to obtain marketing approval for a product candidate will prevent us or a potential collaborator from commercializing the product candidate. We will rely on third parties to assist us in the process of filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. We may not be able to successfully manufacture our products in compliance with applicable requirements such as GMPs. If any of our product candidates receives marketing approval, the accompanying label may limit its approved use more narrowly than we anticipate, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude us from obtaining marketing approval or prevent or limit commercial use. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Any marketing approval that we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be impaired.

Failure to obtain marketing approval in foreign jurisdictions would prevent certain of our product candidates from being marketed in these territories. Any approval we are granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions.

To market and sell our products in the European Union, or EU, and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain approval from the FDA. The regulatory approval process outside the United States generally includes all the risks associated with obtaining approval from the FDA. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, denial of approval in one jurisdiction may impact the ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or our collaborators manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a REMS or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements, among other things. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP. We must also comply with FDA requirements for adverse event reporting for commercial products.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. We could also be subject to other civil or criminal penalties. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

The FDA and other federal and state agencies, including the U.S. DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we market our products for indications other than their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including but not limited to:

- litigation involving patients taking our products;
- restrictions on our products, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approve applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Non-compliance with U.K. and EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the U.K.'s or EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.

Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;

- HIPAA, which created additional federal criminal and civil statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the HITECH Act of 2009, and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, which created annual reporting requirements for manufacturers of drugs, devices, biologicals and medical supplies for certain payments and "transfers of value" provided to covered recipients, including physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and drug pricing; state and local laws requiring the licensure of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

Future legislation, and/or regulations and policies adopted by the FDA, the EMA or comparable regulatory authorities, may increase the time and cost required for us or our collaborators to conduct and complete clinical trials of our current and future product candidates.

The FDA and the EMA have each established regulations to govern the product development and approval process, as have other foreign regulatory authorities. The policies of the FDA, the EMA and other regulatory authorities may change. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but not all its provisions have yet been implemented. Additionally, in August 2017, the FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from the FDA or other regulatory authorities will have on the development of our product candidates.

Recently enacted and future legislation, including relevant provisions of the Inflation Reduction Act, may increase the difficulty and cost for us and our collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

Other federal health reform measures have been proposed and adopted in the United States. For example, the Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. It is unclear how payment reductions or the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. It is also unclear if changes in Medicare payments to providers would impact such providers' willingness to prescribe and administer our products, if approved.

Further, there has been heightened governmental scrutiny over the way companies set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and patient programs, and reform government program reimbursement methodologies for drug products. In particular, the recently passed Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various prescription drugs.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us or our collaborators from being able to generate revenue, attain profitability, or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the former Trump Administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The former Trump Administration also released a "Blueprint", or plan, to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers.

HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On November 20, 2020, CMS issued an interim final rule through the CMS Innovation Center whereby Medicare Part B reimbursement for "certain high-cost prescriptions drugs" would be no more than most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While some of these and other measures may require additional authorization to become effective, members of Congress and the new Biden Administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. For example, the recently enacted Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various prescription drugs. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Risks Related to our Alliance with GSK

Because a portion of our current revenues and near-term projected revenues have historically been derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.

Historically, all of our current and near-term projected revenues have been derived from products under the GSK Agreements. We expect royalties from such products will likely continue to comprise a portion of our revenues in the future. 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.

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

GSK is a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from our interests and those of our 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 stockholders.

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.

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 (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.

General Risks Factors

Unfavorable global economic conditions, whether brought about by material global crises, health epidemics, military conflicts or war, geopolitical and trade disputes or other factors, may adversely affect our business and financial results.

Our business is sensitive to global economic conditions, which can be adversely affected by epidemics and other public health crises, political and military conflict, trade and other international disputes, significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers.

Further, military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and Israel and Palestine) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse

impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short and long-term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber-attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets.

Additionally, the operations of our suppliers and manufacturers may be located in areas that are prone to earthquakes, wildfires and other natural disasters. Such operations and facilities are also subject to the risk of interruption by drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, labor disputes, public health crises, and other events beyond the Company's control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. Such events can create delays or interruptions to the Company's development efforts and inefficiencies in the Company's supply and manufacturing chain. Significant delays in our development efforts could materially impact our ability to obtain regulatory approval and to commercialize our products.

Any public health crisis may affect our operations and those of third parties on which we rely, including our business partners and suppliers. The COVID-19 pandemic has had an adverse impact on the global economy, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic.

Without limiting the foregoing, we have experienced and/or may in the future experience:

- delays in receiving authorization from regulatory authorities to initiate any planned clinical trials, inspections, reviews and approvals of products;
- delays or difficulties enrolling patients in our clinical trials;
- delays in or disruptions to the conduct of preclinical programs and clinical trials;
- constraints on the movement of products and supplies through the supply chain, which can disrupt our ability to conduct clinical trials and develop our products;
- price increases in raw materials and capital equipment, as well as increasing price competition in our markets;
- adverse impacts on our workforce and/or key employees; and
- increased risk that counterparties to our contractual arrangements will become insolvent or otherwise unable to fulfill their contractual obligations.

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 ("U.S. 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 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.

We are subject to evolving and complex tax laws, which may result in additional liabilities and affect our results of operations.

We are subject to income taxes in the U.S. and other jurisdictions, and in the course of our business, we make judgments about the expected tax treatment of various transactions and events. Changes in tax laws, regulations, administrative practices, principles, and interpretations, as well as events that differ from our expectations, have affected and may adversely affect our effective tax rates, cash flows, and/or results of operations. Significant uncertainty currently exists regarding tax proposals introduced by the U.S., including modifications to certain aspects of the Tax Cuts and Jobs Act of 2017, such as the potential repeal or deferral of the provision requiring capitalization of research and development expenses. In addition, tax authorities in the U.S. and other jurisdictions in which we do business routinely examine our tax returns and are intensifying their scrutiny and examinations of profit allocations among jurisdictions, which could unfavorably impact our results of operations. Further actions taken with respect to tax-related matters by associations such as the Organization for Economic Co-operation and Development and the European Commission could influence tax laws in countries in which we operate. Modifications to key elements of the current U.S. or international tax framework could have a significant impact on our effective tax rate, results of operations, and cash flows.

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 COVID-19 has negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. 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 resulting from the COVID-19 pandemic could materially affect our results of operations and financial condition.

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, managed by Sarissa Capital, 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 a portion of our revenues will continue to be derived from our royalty management business and the sales of our products, 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 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.

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, 2023 and December 31, 2023, the high and low sales prices of our common stock as reported on The Nasdaq Global Select Market varied between $10.64 and $16.43 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.

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.

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.

The enactment of proposed or future tax legislation may adversely impact our financial condition and results of operations.

On August 16, 2022, President Biden signed the Inflation Reduction Act, or the IRA. The IRA contains a number of tax related provisions including a 15% minimum corporate income tax on certain large corporations as well as an exercise tax on stock repurchases, both provisions are effective for tax years beginning after December 31, 2022. We are in the process of evaluating the IRA to determine any impact on our financial condition and results of operations in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct risk assessments to identify cybersecurity threats at least annually, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. We devote internal and external resources and designate high-level personnel to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, legal, and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage internal auditors and other third parties in connection with our risk assessment processes. These service providers assist us in designing and implementing our cybersecurity policies and procedures, as well as to monitor and test our safeguards.

During the year ended December 31, 2023, we did not identify any risks from known cybersecurity threats, including because of any prior cybersecurity incidents, that have materially affected us. However, in the future, we may face certain ongoing cybersecurity risks or threats that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, “Risk Factors,” under the heading “Our operations could be disrupted by failure of our information systems or cyber-attacks.”

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our executive team, primarily consisting of Chief Accounting Officer, Chief Financial Officer, and Chief Executive Officer, in conjunction with our information security team and third-party consultants, is primarily responsible in assessing and managing our material risks from cybersecurity threats. The qualifications of our executive and information security teams include a combination of formal education, current trainings and certifications in systems, network, and cybersecurity and over 50 years of combined experience in information technology and cybersecurity matters.

They oversee our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above. The processes by which the executive team is informed about and monitors the prevention, detection, mitigation, and remediation of cybersecurity incidents includes the following:

- They provide briefings to the audit committee regarding our company’s cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.
- In addition, they provide briefings of any significant cybersecurity matters to the board of directors as well as an annual update of cybersecurity risks and activities.

ITEM 2. PROPERTIES

Our headquarters consist of a lease of 2,111 square feet of office space in Burlingame, California, which expires in December 2027. Our other material leased property is a combination of office space and laboratory facility of approximately 20,000 square feet located in Waltham, Massachusetts, which expires in December 2025. We believe that these facilities are sufficient for our current operational needs and that suitable additional space will be available on commercially reasonable terms to accommodate expansion of our operations, if necessary.

ITEM 3. LEGAL PROCEEDINGS

The information called for by this Item is incorporated herein by reference in Item 8. “Financial Statements and Supplementary Data,” Note 13. “Commitments and Contingencies”.

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 14, 2024, there were 63 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.3

Dividends

We have not paid any cash dividends on our common stock since September 30, 2015. The payment of cash dividends in the future will be dependent upon our revenues and earnings, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our board of directors at such time. In addition, our board of directors is not currently contemplating and does not anticipate declaring any stock dividends in the foreseeable future. Further, our ability to declare dividends may be limited by restrictive covenants contained in any of our existing or future indebtedness.

Securities Authorized for Issuance Under Equity Compensation Plans

Securities Authorized for Issuance Under Equity Compensation Plans: See Part III, Item 12 of this Form 10-K for additional information required.

Purchases of Equity Securities by the Issuer

The following table reflects share repurchases of our common stock for the three months ended December 31, 2023:

Period	Total Number of Shares Purchases	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs [1]	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [1]
October 1, 2023 to October 31, 2023	556,406	$ 13.07	556,406	$ 23,131,237
November 1, 2023 to November 30, 2023	287,723	13.61	287,723	19,215,246
December 1, 2023 to December 31, 2023	277,706	15.14	277,706	15,011,394
Total	1,121,835	$ 13.72	1,121,835	

(1) On October 31, 2022, the Board of Directors of Innoviva authorized and approved a stock repurchase program pursuant to which we may purchase up to $100.0 million of our outstanding common stock. The timing and amount of any share repurchases under the share repurchase program will be determined by Innoviva's management in its discretion based on ongoing assessments of the capital needs of the business, the market price of Innoviva's common stock, prevailing stock prices, general market conditions and other considerations. Share repurchases under the program may be made through a variety of methods, which may include open market purchases, privately negotiated transactions, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination thereof or by other means in accordance with federal securities laws. This program has no termination date, may be suspended or discontinued at any time at the Company's discretion and does not obligate the Company to acquire any amount of common stock.

Stock Performance Graph

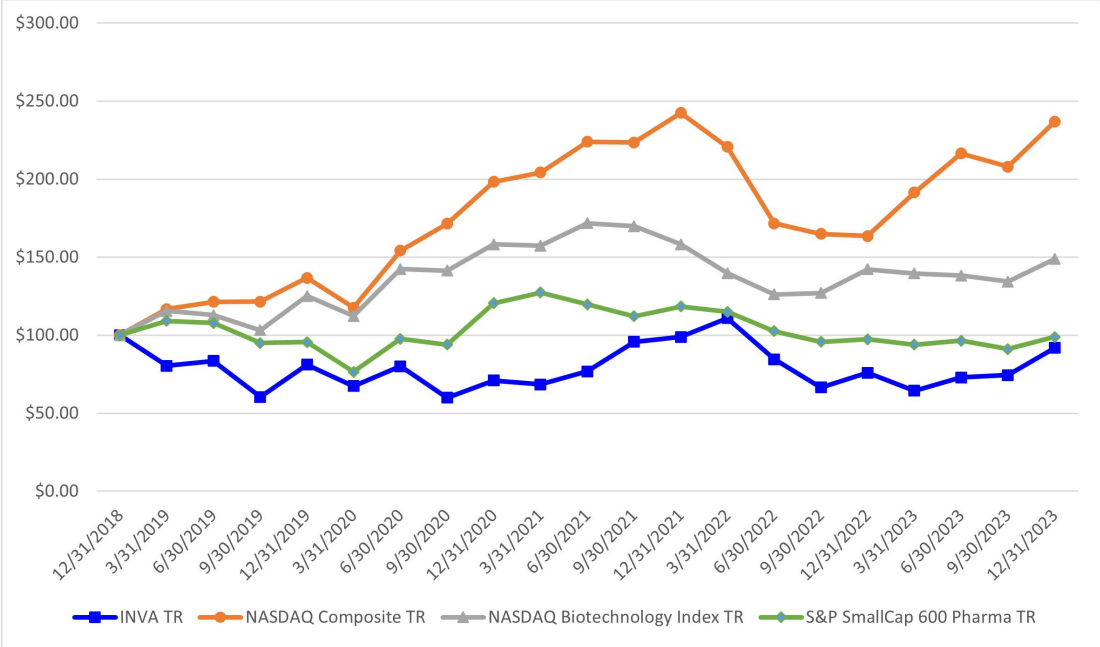
The graph set forth below compares the cumulative total stockholder return on our common stock for the period commencing on December 31, 2018 and ending on December 31, 2023, with the cumulative total return of (i) the Nasdaq Composite Index, (ii) the Nasdaq S&P Small Cap 600 Pharma Index and (iii) the Nasdaq Biotechnology Index over the same period. This graph assumes the investment of $100.00 on December 31, 2017 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, 2018 in stock or index, including reinvestment of dividends.

ITEM 6. [Reserved]

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. (and where context requires, together with its subsidiaries referred to as "Innoviva", the "Company", the "Registrant" or "we" and other similar pronouns) is a company with a portfolio of royalties and innovative healthcare assets. We currently have three primary sets of assets: a royalty portfolio, operating assets in critical care and infectious disease, and other strategic healthcare assets.

Our royalty portfolio contains respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, "UMEC/VI"), and up until July 2022, TRELEGY® ELLIPTA® (the combination FF/UMEC/VI). We sold our 15% ownership interest in Theravance Respiratory Company, LLC ("TRC") on July 20, 2022, and are no longer entitled to receive royalties on sales of TRELEGY® ELLIPTA® products. 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%.

We expanded our portfolio through the acquisition of Entasis Therapeutics Holdings Inc. ("Entasis") on July 11, 2022 and the acquisition of La Jolla Pharmaceutical Company ("La Jolla") on August 22, 2022. Following the acquisitions, our commercial and marketed products include GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (eravacycline) approved for the treatment of complicated intra-abdominal infections in adults. Our new commercial and marketed product, XACDURO® (formerly known as sulbactam-durlobactam or SUL-DUR), was approved by the United States Food and Drug Administration ("FDA") on May 23, 2023 for the treatment of hospital-acquired and ventilator-associated pneumonias caused by *Acinetobacter* in adults. We commenced commercial sales of XACDURO® in the third quarter of 2023. Our development pipeline includes zoliflodacin, an investigational treatment for uncomplicated gonorrhea that reported positive data in a pivotal Phase 3 clinical trial on November 1, 2023. As such, we have a wholly owned robust critical care and infectious disease operating platform with hospital focus.

In addition, we own other strategic healthcare assets, such as a large equity stake in Armata Pharmaceuticals ("Armata"), a leader in development of bacteriophage with potential use across a range of infectious and other serious diseases. We also have economic interests in other healthcare companies.

Our focus on capital allocation and shareholder value maximization has led our company to a meaningful transformation, and 2023 was a significant transition year. In 2022 our financials contained royalty revenues from TRELEGY® ELLIPTA® which was divested mid-year in an economically accretive transaction. Additionally, our acquisition and integration of operating companies further changed the structure of our financials compared to prior years. Through these changes, we believe we are well-positioned to create significant long-term shareholder value.

Our company structure and organization are tailored to our focused activities of managing our respiratory assets partnered with GSK, commercializing our marketed products, developing of our product candidates, optimizing capital allocation, and providing for certain essential reporting and management functions of a public company. As of December 31, 2023, we had 112 employees.

Financial Highlights

- Royalty revenue: Fourth quarter 2023 gross royalty revenue from GSK was $69.6 million and full year was $252.7 million, compared to $54.7 million for the fourth quarter of 2022 and $253.4 million for the full year 2022.

• Net Product Sales: Fourth quarter 2023 net product sales and license revenue were $19.7 million, which included $13.1 million from GIAPREZA®, $5.2 million from XERAVA®, and $1.4 million from XACDURO®, compared to $14.6 million for the fourth quarter of 2022. Full year 2023 net product sales and license revenue was $71.6 million, which included $41.3 million from GIAPREZA®, $17.3 million from XERAVA®, $2.0 million from XACDURO®, and $11.0 million in milestone payments from our partners.

• Equity and long-term investments: Fourth quarter and full year 2023 change in fair values of equity and long-term investments of $25.5 million and $88.5 million, respectively, was primarily attributable to Armata share price appreciation.

• Net income: Fourth quarter 2023 net income was $61.5 million, or $0.97 basic per share, compared to a net loss of $68.3 million, or $(0.98) basic per share, for the fourth quarter 2022, driven primarily by higher revenue and positive impact of change in fair values of equity. Full year 2023 net income was $179.7 million, or $2.75 basic per share, compared to net income of $213.9 million, or $3.07 basic per share, for the full year 2022.

• Share repurchase: During the fourth quarter 2023, Innoviva repurchased 1,121,835 shares of its outstanding common stock for $15.4 million. During the year 2023, Innoviva repurchased 6,173,565 shares of its outstanding common stock for $76.5 million. Approximately $15 million of the authorized program remains outstanding as of year-end.

• Cash and cash equivalents: Totaled $193.5 million. Royalty and net product sales receivables totaled $84.1 million as of December 31, 2023.

Key 2023 R&D Highlights

• Zoliflodacin: potential first-in-class oral antibiotic to treat uncomplicated gonorrhea

  o In November 2023, in collaboration with The Global Antibiotic Research & Development Partnership (GARDP), Innoviva announced that zoliflodacin, a first-in-class antibiotic, met its primary endpoint in a global pivotal phase 3 clinical trial for the treatment of uncomplicated gonorrhea. The Company expects a New Drug Application to be submitted to the U.S. FDA in the next twelve months.

• XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use: targeted antibacterial for HABP/VABP caused by *Acinetobacter*

  o In May 2023, the U.S. Food and Drug Administration (FDA) approved XACDURO® for use in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

  o Earlier in May, *The Lancet Infectious Diseases* published detailed results from the pivotal Phase 3 ATTACK trial of sulbactam-durlobactam.

Update on Strategic Healthcare Assets

• Our portfolio of strategic assets under the Company's various subsidiaries was valued at $561.0 million as of December 31, 2023. In fourth quarter 2023, Innoviva invested an additional $5.0 million in one of our assets, Gate Neurosciences, to support its strategy of developing next generation targeted CNS therapies.

Collaborative Arrangements with GSK

LABA Collaboration

In November 2002, we entered into the LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disorder ("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 approval and launch milestone payments 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 that are expected to continue over the life of the agreement. The milestone fees paid to GSK were recognized as capitalized fees, 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. On sales of ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%. We no longer receive royalties on sales of TRELEGY® ELLIPTA® after we sold our royalty rights along with the sale of our ownership in TRC in July 2022.

As mentioned above, on July 20, 2022, we sold our ownership interest in TRC, which received royalty payments from GSK stemming from sales of TRELEGY® ELLIPTA®. We retained our royalty rights with respect to RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

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 are provided free of charge to us. Sarissa Capital is considered to be a related party due to its investment in Innoviva's common stock and its representation on our board of directors.

Partnership Agreement

On December 11, 2020, Innoviva Strategic Partners LLC ("Strategic Partners"), our wholly owned subsidiary, 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 $300.0 million initial contribution into the Partnership. The Partnership was formed for the purposes of investing in equity 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.

In May 2021, Strategic Partners received a distribution of $110.0 million from the Partnership to provide funding to Innoviva for a strategic repurchase of Innoviva common shares held by GSK. On March 30, 2022, Strategic Partners made an additional capital contribution of $110.0 million to the Partnership pursuant to the letter agreement entered into between Strategic Partners, the Partnership and Sarissa Capital Fund GP LP on May 20, 2021. The capital contribution is subject to a 36-month lock-up period from the contribution date.

The lock-up period for our initial contribution of $190.0 million expired in December 2023. Strategic Partners did not elect to make a withdrawal in 2023, thereby extending the lock-up period and withdrawal elections into subsequent years.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Business Combinations

We use the acquisition method of accounting under Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*. Each acquired company's operating results are included in our consolidated financial statements starting on the acquisition date. The purchase price is equivalent to the fair value of consideration transferred. Tangible and identifiable intangible assets acquired, liabilities assumed and any noncontrolling interest in the acquiree as of the acquisition date are recorded at the acquisition date fair value. Goodwill is recognized for the excess of purchase price over the net fair value of assets acquired and liabilities assumed.

Amounts allocated to assets and liabilities are based upon fair values. Such valuations require us to make significant estimates and assumptions, especially with respect to the identifiable intangible assets. We make estimates of fair value based upon assumptions believed to be reasonable and that of a market participant. Significant estimates and assumptions may involve projected future revenues, earnings, cash flows, estimated probabilities of certain milestone achievements, discount rates, asset lives, among other items. Our estimates may also impact our deferred tax assets and liabilities. Unanticipated events and circumstances may occur that may affect the accuracy and validity of such assumptions, estimates or actual results. Our estimates are based on available historical information as well as future expectations, and the estimates are inherently uncertain. The separately identifiable intangible assets generally include marketed products, in-process research and development and collaboration agreement.

Revenue Recognition from Royalties

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. The net sales reports provided by our partner are based on its methodology and assumptions to estimate rebates and returns, which it monitors and adjusts regularly in light of contractual and legal obligations, historical trends, past experience and projected market conditions. Our partner may make significant adjustments to its sales based on actual results recorded, which could cause our royalty revenue to fluctuate. We conduct periodic royalty audits to evaluate the information provided by our partner. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Revenue Recognition from Product Sales

We started recognizing revenue from product sales as a result of our acquisition of La Jolla. We apply the guidance on principal versus agent considerations under ASC Topic 606, *Revenue from Contracts with Customers*, to determine the appropriate treatment for the transactions between us and third parties. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as product sales.

Prior to recognizing any revenue from product sales, we identify the contract, performance obligations, and transaction price, and allocate the transaction price to the performance obligations. Revenue from product sales is recognized when our customers obtain control of the product and is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and rebates. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These items may include:

- Chargebacks: Chargebacks are discounts we provide to distributors in the event that the sales prices to end users are below the distributors' acquisition price. This may occur due to a direct contract with a health system, a group purchasing organization ("GPO") agreement or a sale to a government facility. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to our customers.
- Discounts: We offer customers various forms of incentives and consideration, including prompt-pay and other discounts. We estimate discounts primarily based on contractual terms. These discounts are recorded as a reduction of revenue on delivery to our customers.
- Returns: We offer customers a limited right of return, generally for damaged or expired product. We estimate returns based on an internal analysis, which includes actual experience. The estimates for returns are recorded as a reduction of revenue on delivery to our customers.
- Rebates: We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within three months after the quarter in which product was sold. Additionally, we may offer customer incentives and consideration in the form of volume-based or other rebates. The estimates for rebates are recorded as a reduction of revenue on delivery to our customers.

We continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly.

Capitalized Fees Paid

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 of past, current and future sales and trends, there have been no indicators of impairment and no impairment charges have been recorded on the Capitalized Fees as of December 31, 2023.

Variable Interest Entities

The primary beneficiary of a variable interest entity ("VIE') is required to consolidate the assets and liabilities of the VIE. When we obtain a variable interest in another entity, we assess at the inception of the relationship and upon occurrence of certain significant events whether the entity is a VIE and, if so, whether we are the primary beneficiary of the VIE based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. To determine whether a variable interest that we hold could potentially be significant to the VIE, we consider both qualitative and quantitative factors regarding the nature, size and form of our involvement with the VIE.

To assess whether we have the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, we consider all the facts and circumstances, including our role in establishing the VIE and our ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the Board of Directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether we have the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, we consider all of our economic interests that are deemed to be variable interests in the VIE. This assessment requires us to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE.

Equity and Long-Term Investments

Our investments in Armata include a convertible note (the "Armata Convertible Note") and a term loan (the "Armata Term Loan"), both of which are classified as Level 3 financial instruments. The Armata Convertible Note is measured at fair value using a Monte Carlo simulation model with the probability of certain qualified events and the assumptions of risk-free rate, volatility of stock price and timing of certain qualified events. We measure the Armata Term Loan at fair value using an income approach based on the discounted value of expected future cash flows.

Our Level 3 financial instruments include the Gate Neurosciences Inc. ("Gate") convertible promissory note and private placement positions held by ISP Fund LP as these securities are not publicly traded and the assumptions used in the valuation model for valuing these securities are based on significant unobservable and observable inputs including those of publicly traded peer companies. We measure the Gate convertible promissory note at fair value using a Monte Carlo simulation model with the probability of certain qualified events and the assumptions of equity value of Gate, risk-free rate, expected stock price, volatility of its peer companies, and the time until a financing is raised. Valuations models applied for the private placement positions held by ISP Fund LP may include the Black-Scholes-Merton pricing model, the Monte Carlo simulation model and other applicable valuation models. Key assumptions involve inputs to the Black-Scholes-Merton pricing model, probability rates of certain events and scenarios applied in the Monte Carlo simulation model and discount rates, as appropriate. The Monte Carlo simulation model also incorporates assumptions made based on transaction details such as the security's stock price, the expected term, maturity, risk-free interest rates and dividend yield, as well as volatility.

We also hold preferred stock warrants in InCarda Therapeutics Inc. ("InCarda"), a privately held, clinical-stage biopharmaceutical company. The preferred stock warrants are classified as Level 3 financial instruments and recorded at fair value subject to remeasurement at each balance sheet 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 public peer companies. As of December 31, 2023, the fair value of these warrants was minimal.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors described below.

- Adoption of Accounting Standards Update ("ASU") 2020-06 effective January 1, 2022;
- Accounting consolidation of Entasis on February 17, 2022 and purchase of remaining minority interest in Entasis on July 11, 2022;
- Sale of our 15% ownership interest in TRC on July 20, 2022; and
- Acquisition of La Jolla on August 22, 2022.

Refer to Note 12, "Debt", to the Consolidated Financial Statements for more information related to the adoption of ASU 2020-06. Refer to Note 5, "Consolidated Entities and Acquisitions", to the Consolidated Financial Statements for more information related to our acquisitions of Entasis and La Jolla and the sale of our ownership interest in TRC.

Results of Operations

Net Revenue

Royalty Revenue

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

	Year Ended December 31,			Change			
				2023		2022	
(In thousands)	2023	2022	2021	$	%	$	%
Royalties – RELVAR/BREO	$ 208,042	$ 215,034	$ 234,066	$ (6,992)	(3)%	$ (19,032)	(8)%
Royalties – ANORO	44,627	38,405	44,935	6,222	16%	(6,530)	(15)%
Royalties – TRELEGY	—	72,029	126,688	(72,029)	(100)%	(54,659)	(43)%
Total royalties	252,669	325,468	405,689	(72,799)	(22)%	(80,221)	(20)%
Less: amortization of capitalized fees paid	(13,823)	(13,823)	(13,823)	—	*	—	*
Total net royalty revenue	$ 238,846	$ 311,645	$ 391,866	$ (72,799)	(23)%	$ (80,221)	(20)%

* Not Meaningful

Total royalty revenue, net, decreased to $238.8 million for the year ended December 31, 2023, compared to $311.6 million for the year ended December 31, 2022. The decrease in total net royalty revenue was primarily due to the sale of our ownership interest in TRC, which received royalties stemming from sales of TRELEGY® ELLIPTA®.

Total royalty revenue, net, decreased to $311.6 million for the year ended December 31, 2022, compared to the year ended December 31, 2021. The decrease in total net royalty revenue was primarily due to the sale of our ownership interest in TRC, which received royalties stemming from sales of TRELEGY® ELLIPTA®. Royalties for RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® decreased due to pricing pressures in the U.S. market and foreign currency rate changes.

Net Product Sales

Net product sales for the year ended December 31, 2023 was $60.6 million, consisting of net sales of GIAPREZA®, XERAVA® and XACDURO® for $41.3 million, $17.3 million, and $2.0 million, respectively. We derived approximately 91% of our net product sales for the same period from customers located in the U.S. and 9% from the rest of the world.

Net product sales we recognized from the date of acquisition of La Jolla, which occurred on August 22, 2022, to December 31, 2022 was $19.7 million, consisting of net sales of GIAPREZA® and XERAVA® for $14.2 million and $5.5 million, respectively. We derived approximately 96% of our net product sales for the same period from customers located in the U.S. and 4% from the rest of the world.

License Revenue

We recognized $8.0 million in license revenue for the year ended December 31, 2023 as a result of achievement of a regulatory milestone under our license agreement with Everest. We also recognized $3.0 million in license revenue as a result of achievement of a regulatory milestone under our license and collaboration agreement with Zai Lab.

Research & Development

Research and development expenses, as compared to the prior year period, were as follows:

	Year Ended December 31,			Change 2023		Change 2022	
(In thousands)	2023	2022	2021	$	%	$	%
Research and development	$ 33,922	$ 41,432	$ 576	$ (7,510)	(18)%	$ 40,856	*

* Not Meaningful

Research and development expenses consisted of the following:

	Year Ended December 31,			Change 2023		Change 2022	
(In thousands)	2023	2022	2021	$	%	$	%
External services	$ 20,051	$ 24,666	$ 576	$ (4,615)	(19)%	$ 24,090	*
Compensation and related personnel costs	10,081	13,863	—	(3,782)	(27)%	13,863	*
Facilities related	2,483	2,255	—	228	10%	2,255	*
Other	1,307	648	—	659	102%	648	*
Total research and development expenses	$ 33,922	$ 41,432	$ 576	$ (7,510)	(18)%	$ 40,856	*

* Not Meaningful

Research and development expenses for the year ended December 31, 2023 were mainly attributable to our product development efforts for XACDURO®. Research and development expenses for the year ended December 31, 2022 were mainly attributable to product development efforts of Entasis that we recognized from February 17, 2022. Research and development expenses for the year ended December 31, 2023 decreased compared to the same period in 2022 primarily due to the FDA approval of XACDURO® in May 2023 and resource reallocation from the research development function to general and administrative function after the FDA approval. External services costs consist primarily of fees paid to consultants, contractors and contract manufacturing organizations.

Research and development expenses for the year ended December 31, 2021 were attributable to the product development efforts of Pulmoquine Therapeutics Inc., which was dissolved at the end of 2021.

Selling, General & Administrative

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

	Year Ended December 31,			Change 2023		Change 2022	
(In thousands)	2023	2022	2021	$	%	$	%
Selling, general and administrative	$ 98,232	$ 63,538	$ 16,187	$ 34,694	55%	$ 47,351	293%

Selling, general and administrative expenses increased by $34.7 million for the year ended December 31, 2023, compared to the year ended December 31, 2022, mainly attributable to the resource reallocation from the research development function to general and administrative function after the FDA approval of XACDURO®. Selling, general and administrative expenses for the year ended December 31, 2023 also reflect certain full-year expenses of Entasis which we started consolidating on February 17, 2022 and of La Jolla, which we acquired in August 22, 2022.

Selling, general and administrative expenses increased by $47.4 million for the year ended December 31, 2022, compared to the year ended December 31, 2021, mainly attributable to the consolidation of Entasis' operating expenses and La Jolla's operating expenses as previously mentioned.

Interest and Dividend Income and Other Expense, Net

Interest and dividend income and other expense, net, as compared to the prior years, were as follows:

	Year Ended December 31,			Change			
				2023		2022	
(In thousands)	2023	2022	2021	$	%	$	%
Interest and dividend income	$ (15,818)	$ (6,369)	$ (1,839)	$ (9,449)	148%	$ (4,530)	246%
Other expense, net	4,969	3,373	3,626	1,596	47%	(253)	*

* Not Meaningful

Interest and dividend income increased for the year ended December 31, 2023, compared to the year ended December 31, 2022, due to higher interest rates and higher average balances of our cash equivalents, money market funds and other interest-bearing investments.

Interest and dividend income increased for the year ended December 31, 2022, compared to the year ended December 31, 2021, due to higher interest rates and higher average balances of our cash equivalents, money market funds and other interest-bearing investments. Other expense, net, primarily consisted of expenses incurred by ISP Fund LP.

Interest Expense

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

	Year Ended December 31,			Change			
				2023		2022	
(In thousands)	2023	2022	2021	$	%	$	%
Interest expense	$ 19,157	$ 15,789	$ 19,070	$ 3,368	21%	$ (3,281)	(17)%

The interest expense included the contractual interest expense and the amortization of debt issuance costs for our convertible subordinated notes due 2023 (the “2023 Notes”), our convertible senior notes due 2025 (the “2025 Notes”) and our convertible senior notes due 2028 (the “2028 Notes”), as well as effective interest expense on our deferred royalty obligation. The increase in 2023, compared to the year ended December 31, 2022, was mainly due to the interest expense on our deferred royalty obligation from the acquisition of La Jolla.

The change in interest expense for the year ended December 31, 2022, compared to the year ended December 31, 2021, was primarily due to the adoption of ASU 2020-06, which simplifies the accounting for convertible debt instruments. As a result of the adoption, the debt discount associated with the cash settlement feature of the 2025 Notes was adjusted to zero as of January 1, 2022. Interest expense for the year ended December 31, 2022 included the contractual interest expense and the amortization of debt issuance costs for our 2023 Notes, the 2025 Notes and 2028 Notes. Interest expense for the year ended December 31, 2021 included the amortization of debt discount in addition to the contractual interest expense and the amortization of debt issuance costs for our 2023 Notes and 2025 Notes. The decrease in interest expense as a result of the adoption of ASU 2020-06 was partially offset by a higher debt balance and interest expense incurred for the deferred royalty obligation from the acquisition of La Jolla.

Loss on Debt Extinguishment

For the year ended December 31, 2022, we recognized a loss of $20.7 million due to the total premium payment of $20.4 million and the write-off of $0.3 million debt issuance costs in connection with the repurchase of $144.8 million aggregate principal amount of our 2023 Notes in March 2022.

Gain on Sale of TRC

We recognized a net gain of $266.7 million for the year ended December 31, 2022 due to the sale of our ownership interest in TRC to Royalty Pharma, consummated on July 20, 2022.

Changes in Fair Values of Equity Method Investments and Equity and Long-Term Investments

Changes in fair values of equity method investments and equity and long-term investments, net, as compared to the prior years, were as follows:

	Year Ended December 31,			Change			
				2023		2022	
(In thousands)	2023	2022	2021	$	%	$	%
Changes in fair values of equity method investments, net	$ (77,392)	$ 161,749	$ (84,392)	$ (239,141)	(148)%	$ 246,141	(292)%
Changes in fair values of equity and long-term investments, net	$ (11,129)	$ (8,462)	$ (6,638)	$ (2,667)	32%	$ (1,824)	27%

The changes in fair values of equity method investments for the year ended December 31, 2023 were favorable mainly due to Armata's higher stock prices during this period. We recorded $77.4 million in unrealized gains, $152.5 million in unrealized losses and $78.7 million in unrealized gains associated with our equity method investments in Armata for the years ended December 31, 2023, 2022 and 2021, respectively. The changes in fair values of equity method investments for the years ended December 31, 2022 and 2021 also include $9.2 million in unrealized losses and $5.7 million in unrealized gains, respectively, we recorded from our then equity method investments in Entasis. Refer to Note 6, "Equity and Long-Term Investments and Fair Value Measurements", to the Consolidated Financial Statements for more information.

The changes in fair values of equity and long-term investments year over year reflect the realized gains and losses and net unrealized gains and losses in our strategic investments in Armata, InCarda, and Gate, and those investments managed by ISP Fund LP. We recorded $23.8 million in unrealized gain for the year ended December 31, 2023 related to other long-term investments we made in Armata in 2023.

Income Taxes

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

	Year Ended December 31,			Change			
				2023		2022	
(In thousands)	2023	2022	2021	$	%	$	%
Income tax expense, net	$ 14,376	$ 66,687	$ 76,439	$ (52,311)	(78)%	$ (9,752)	(13)%

As of December 31, 2023, 2022 and 2021, we had net operating loss carryforwards for federal income taxes of $543.5 million, $411.5 million and $92.9 million, respectively. As of December 31, 2023, 2022 and 2021, we also had state net operating loss carryforwards of approximately $1.0 billion, $955.3 million and $648.6 million, respectively, which will expire beginning 2029. As of December 31, 2021, we had federal research and development tax credit carryforwards of $42.1 million. We did not have such federal research and development tax credit carryforwards as of December 31, 2023 and 2022. As of December 31, 2023, we had state research and development tax credits of $33.3 million.

For the year ended December 31, 2023, 2022 and 2021, we recognized $14.4 million, $66.7 million and $76.4 million of income tax expense, respectively, mainly based on the taxable income generated during those years.

We had total unrecognized tax benefits of $19.4 million as of December 31, 2023. Our total unrecognized tax benefits as of December 31, 2022 and December 31, 2021 were $16.3 million and $14.9 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 of the Company through December 31, 2023 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. If we ever undergo an 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.

As a result of the acquisition of Entasis, we conducted a study of Entasis' ownership changes and estimated that we will be able to utilize $155.6 million of its federal net operating losses, which are subject to annual limitations.

As a result of the acquisition of La Jolla, we also performed an analysis of its ownership changes and estimated that we will be able to utilize $309.5 million of its federal net operating losses, which are subject to annual limitations.

In December 2021, the Organization for Economic Cooperation and Development ("OECD") enacted model rules for a new global minimum tax framework ("BEPS Pillar Two"), and various governments around the world have enacted, or are in the process of enacting legislation. We are in the process of evaluating whether and when these new rules may come into effect and apply to us. We plan to treat the tax if any as a period cost. We do not believe that the Pillar Two rules apply to us yet. As such, the potential future quantitative impact of the enacted or substantively enacted legislation is not yet reasonably estimable.

Net Income Attributable to Noncontrolling Interest

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

	Year Ended December 31,			Change			
				2022		2022[1]	
(In thousands)	2023	2022[1]	2021	$	%	$	%
Net income attributable to noncontrolling interest	$ —	$ 6,341	$ 102,983	$ (6,341)	(100)%	$ (96,642)	(94)%

[1] The year ended December 31, 2022 represents the period from the initial date of consolidation of Entasis on February 17, 2022 to the date of the acquisition of Entasis on July 11, 2022, and the period from January 1, 2022 through the date of the sale of our ownership interest in TRC on July 20, 2022.

Net income attributable to noncontrolling interests for the year ended December 31, 2022 was $6.3 million compared to $103.0 million for the year ended December 31, 2021, or a decrease of $96.6 million, which was mainly due to lower net income attributable to the sale of our ownership interest in TRC, offset with net loss attributable to Entasis' noncontrolling interest.

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, 2023, we generated gross royalty revenues of $252.7 million and net product sales revenues of $60.6 million. Cash and cash equivalents totaled $193.5 million, royalties receivable from GSK totaled $69.6 million and accounts receivable associated with our product sales totaled $14.5 million, as of December 31, 2023.

As of December 31, 2023, we had two outstanding convertible notes, the 2025 Notes and the 2028 Notes, in an aggregate principal amount of $453.5 million, of which $192.5 million and $261.0 million will become due in August 2025 and March 2028, respectively. Future interest payments associated with these notes total $34.6 million.

On October 31, 2022, our Board of Directors authorized a share repurchase program under which we may repurchase up to $100.0 million of Innoviva's outstanding shares of common stock. As of December 31, 2023, we have repurchased Innoviva common stock in the open market for total price of approximately $84.2 million. This program has no termination date, may be suspended or discontinued at any time at our discretion and does not obligate us to acquire any amount of common stock.

In May 2021, Strategic Partners received a distribution of $110.0 million from the Partnership to provide funding to Innoviva for a strategic repurchase of Innoviva common shares held by GSK. On March 30, 2022, Strategic Partners made an additional capital contribution of $110.0 million to the Partnership pursuant to the letter agreement entered into between Strategic Partners, the Partnership and Sarissa Capital Fund GP LP on May 20, 2021. The capital contribution is subject to a 36-month lock-up period from the contribution date.

The lock-up period for our initial contribution of $190.0 million expired in December 2023. Strategic Partners did not elect to make a withdrawal in 2023, thereby extending the lock-up period and withdrawal elections into subsequent years.

Adequacy of Cash Resources to Meet Future Needs

We believe that our cash and cash equivalents will be sufficient to meet our anticipated debt service and operating needs, as well our ongoing share repurchase program, for at least the next 12 months based upon current operating plans and financial forecasts. Our long-term capital requirements will depend on many factors including the amount of our royalty revenues, sales growth of our currently marketed products, timing of regulatory approval of our product candidates and outcome of our acquisitions and strategic investments. 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 in the form of public or private equity offerings or debt financings 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 privately negotiated repurchases, tender offers, redemptions, amendments, or otherwise, all allowable with the terms of our debt agreements.

Cash Flows

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

	Year Ended December 31,			Change	
(In thousands)	**2023**	**2022**	**2021**	**2023**	**2022**
Net cash provided by operating activities	$ 141,064	$ 201,726	$ 363,813	$ (60,662)	$ (162,087)
Net cash provided by (used in) investing activities	(66,761)	(56,634)	43,722	(10,127)	(100,356)
Net cash used in financing activities	(171,839)	(55,568)	(452,497)	(116,271)	396,929

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2023 was $141.1 million, consisting primarily of our net income of $179.7 million, partially offset by net non-cash items of $13.9 million and net changes in operating assets and liabilities of $24.8 million. Non-cash items included a $88.5 million net increase in fair values of equity method investments and equity and long-term investments, partially offset by $27.2 million in inventory fair value adjustments included in cost of products sold, $21.8 million in amortization of acquired intangible assets, $13.9 million of amortization of capitalized fees and depreciation of property and equipment, $5.8 million in stock-based compensation expense, $4.4 million of deferred income taxes and $2.1 million in amortization of debt discount and issuance costs. The changes in operating assets and liabilities included increases in receivables from collaboration arrangements of $14.9 million, inventories of $12.0 million, accounts receivable of $5.1 million, other assets of $3.0 million and a decrease in personnel-related, interest and other accrued expenses of $2.4 million, partially offset by a decrease in prepaid expenses of $7.9 million and increases in accounts payable of $3.8 million and income tax payable of $1.7 million.

Cash provided by operating activities for the year ended December 31, 2022 was $201.7 million, consisting primarily of our net income of $220.3 million and net changes in operating assets and liabilities of $6.9 million, partially offset by net non-cash items of $25.4 million. Non-cash items included a net gain of $266.7 million recognized on the sale of TRC, partially offset by net non-cash charges of $241.3 million. Non-cash charges included a $153.3 million net decrease in fair values of equity method investments and equity and long-term investments, $25.0 of deferred income taxes, $13.9 million of amortization of capitalized fees and depreciation of property and equipment and $5.6 million in amortization of acquired intangible assets, $20.7 million in loss on the extinguishment of debt, $7.3 million in stock-based compensation expense, $10.0 million in inventory fair value adjustments included in cost of products sold and $2.1 million in the amortization of debt discount and issuance costs. The changes in operating assets and liabilities included an increase in prepaid expenses of $21.4 million, a decrease in receivables from collaboration arrangements of $13.3 million and increases of $11.9 million and $10.0 million in accrued personnel-related expenses and other accrued liabilities and in income tax payable, respectively.

Cash provided by operating activities for the year ended December 31, 2021 was $363.8 million, consisting primarily of our net income of $368.8 million, adjusted for non-cash items such as $76.4 million of deferred income taxes, $13.8 million of depreciation and amortization, $9.1 million amortization of debt discount and issuance costs, $2.0 million of stock-based compensation expense, partially offset by a $89.3 million net increase in fair values of equity method investments and equity and long-term investments and an increase in receivables from collaborative arrangements of $16.8 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 of $66.8 million included $65.1 million for purchases trading securities, $31.2 million for purchases of equity investments managed by ISP Fund LP, $41.3 million in net purchases and sales of other investments managed by ISP Fund LP and $1.2 million for purchases of equity and long-term investments. Net cash used in investing activities was partially offset by $72.5 million in sales of equity investments managed by ISP Fund LP.

Net cash used in investing activities for the year ended December 31, 2022 of $56.6 million included $159.1 million in cash paid for the acquisition of La Jolla, net of cash acquired, $58.7 million in purchases of equity and long-term investments, $60.9 million in purchases of equity investments managed by ISP Fund LP, $50.0 million in purchases of a trading security managed by ISP Fund LP and $23.4 million in net purchases and sales of other investments managed by ISP Fund LP. Net cash used in investing activities was partially offset by $248.2 million in net proceeds from the sale of our ownership interest in TRC, $24.3 million in sales of equity investments managed by ISP Fund LP and $23.1 million in cash acquired through the consolidation of Entasis.

Net cash provided by investing activities for the year ended December 31, 2021 of $43.7 million was primarily due to $110.0 million net cash inflow from $301.0 million sales and $191.0 million purchases of equity and other investments managed by ISP Fund LP, offset by $66.3 million in purchases of various investment instruments including, but not limited to, common stock, warrants, convertible debt investment, money market funds and other securities.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 of $171.8 million consist mainly of the repayments of $96.2 million upon maturity of the 2023 Notes in January 2023 and $75.7 million for the repurchases of our common stock under the current stock repurchase program.

Net cash used in financing activities for the year ended December 31, 2022 of $55.6 million included $165.1 million for the repurchase of convertible subordinated notes due 2023, $69.8 million in distributions to noncontrolling interest, $43.9 million for the purchase of Entasis noncontrolling interest, $21.0 million for purchases of capped call options associated with our 2028 Notes and $8.5 million for the repurchase of common stock. Net cash used in financing activities was partially offset by $252.5 million in net proceeds from the issuance of our 2028 Notes.

Net cash used in financing activities for the year ended December 31, 2021 of $452.5 million was primarily due to a $394.1 million repurchase of our common stock from GSK and $59.5 million in distributions to noncontrolling interest.

Contractual Obligations

As of December 31, 2023, our notes payable obligation included $192.5 million related to our 2025 Notes and $261.0 million related to our 2028 Notes, which are due in 2025 and 2028, respectively. Under the terms of the 2025 Notes and 2028 Notes, we will make interest payments of 2.5% and 2.125%, respectively, of outstanding principal. Refer to Note 12, “Debt” to the Consolidated Financial Statements for more information.

Our short-term and long-term obligations also include contractual payments related to our operating leases amounting to $3.1 million, with approximately $1.4 million payable through December 31, 2024 and 2025 and approximately $0.1 million payable in each of the years 2026 and 2027. Refer to Note 13, “Commitments and Contingencies” to the Consolidated Financial Statements for more information.

As part of our acquisition of La Jolla, we recognized its deferred royalty obligation in connection with La Jolla Royalty Agreement with HCR. Under the terms of the Agreement, HCR is entitled to receive quarterly royalties on worldwide net sales of GIAPREZA® until either January 1, 2031 or when the maximum aggregate royalty payments have been made, whichever occurs first. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. The current maximum royalty rate is 14%. Starting January 1, 2024, the maximum royalty rate was increased to 18% based on the terms of the Agreement. The La Jolla Royalty Agreement is subject to maximum aggregate royalty payments to HCR of $225.0 million.

Additionally, we have certain contingent payment obligations under various in-license agreements which we are required to make royalty payments or milestone payments upon successful completion and achievement of certain milestones. Refer to Note 4, “License and Collaboration Arrangements” to the Consolidated Financial Statements for more information.

We also enter into agreements in the normal course of business with vendors for manufacturing, clinical trials and preclinical studies, and other services and products for operating purposes.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2023, our debt bears fixed interest rates and we had no outstanding debt with variable interest rates. Our cash flows on these debt obligations are not subject to variability as a result of changes in interest rates.

We are exposed to changes in the fair value of certain of our investments in equity and debt securities. Fluctuations in the underlying fair value of the investments could result in material gains or losses. Refer to Note 6 “Equity and Long-Term Investments and Fair Value Measurements” to the Consolidated Financial Statements for more information.

Inflation has increased during the period covered by this Annual Report on Form 10-K and could continue to increase for the near future. Inflationary factors, such as increases in the cost of our raw materials, supplies, interest rates and overhead costs may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future if inflation rates continue to rise. Significant adverse changes in inflation and prices in the future could result in material losses.

We may face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars, including contracts with international vendors related to raw material purchases. Our royalty revenue from RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® is also indirectly exposed to foreign exchange risk as GSK also markets and sells the products outside the U.S. The majority of our cash and cash equivalents, investments, and the majority of our vendor relationships are denominated in U.S. dollars. Therefore, we do not believe that the risk of a significant impact on our operating income from foreign currency fluctuations is substantial.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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INNOVIVA, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 193,513	$ 291,049
Accounts receivable	14,454	9,401
Receivables from collaboration arrangements	69,621	54,672
Inventory	40,737	55,897
Prepaid expenses	21,630	29,559
Other current assets	4,264	2,933
Total current assets	344,219	443,511
Property and equipment, net	483	170
Equity method investments	116,546	39,154
Equity and long-term investments	444,432	363,859
Capitalized fees paid, net	83,784	97,607
Right-of-use assets	2,536	3,265
Goodwill	17,905	26,713
Intangible assets	230,335	252,919
Other assets	3,267	4,299
Total assets	$ 1,243,507	$ 1,231,497
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$ 6,717	$ 2,939
Accrued personnel-related expenses	7,020	8,022
Accrued interest payable	3,422	4,359
Deferred revenue	1,277	2,094
Convertible subordinated notes due 2023, net of issuance costs	—	96,193
Income tax payable	—	154
Other accrued liabilities	19,698	21,207
Total current liabilities	38,134	134,968
Long-term debt, net of discount and issuance costs	446,234	444,180
Other long-term liabilities	71,870	70,918
Deferred tax liabilities, net	563	5,771
Income tax payable, long-term	11,751	9,872
Commitments and contingencies (Note 13)		
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, 63,307 and 69,188 issued and outstanding as of December 31, 2023 and December 31, 2022 respectively	633	692
Treasury stock: at cost, 32,005 shares as of December 31, 2023 and 2022	(393,829)	(393,829)
Additional paid-in capital	1,093,340	1,163,836
Accumulated deficit	(25,189)	(204,911)
Total stockholders' equity	674,955	565,788
Total liabilities and stockholders' equity	$ 1,243,507	$ 1,231,497

See accompanying notes to consolidated financial statements.

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INNOVIVA, INC.
CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share data)

	Year Ended December 31,		
	2023	2022	2021
Revenue:			
Royalty revenue, net of amortization of capitalized fees paid of $ 13,823 in each of the years ended December 31, 2023, 2022 and 2021	$ 238,846	$ 311,645	$ 391,866
Net product sales	60,617	19,694	—
License revenue	11,000	—	—
Total revenue	310,463	331,339	391,866
Expenses:			
Cost of products sold (inclusive of amortization of inventory fair value adjustments, excluding amortization of intangible assets)	41,040	13,793	—
Cost of license revenue	1,600	—	—
Selling, general and administrative	98,232	63,538	16,187
Research and development	33,922	41,432	576
Amortization of acquired intangible assets	21,784	5,581	—
Gain on sale of Theravance Respiratory Company, LLC (“TRC”)	—	(266,696)	—
Loss on extinguishment of debt	—	20,662	—
Changes in fair values of equity method investments, net	(77,392)	161,749	(84,392)
Changes in fair value of equity and long-term investments, net	(11,129)	(8,462)	(6,638)
Interest and dividend income	(15,818)	(6,369)	(1,839)
Interest expense	19,157	15,789	19,070
Other expense, net	4,969	3,373	3,626

Total expenses, net	116,365	44,390	(53,410)
Income before income taxes	194,098	286,949	445,276
Income tax expense, net	14,376	66,687	76,439
Net income	179,722	220,262	368,837
Net income attributable to noncontrolling interests	—	6,341	102,983
Net income attributable to Innoviva stockholders	$ 179,722	$ 213,921	$ 265,854
Basic net income per share attributable to Innoviva stockholders	$ 2.75	$ 3.07	$ 3.24
Diluted net income per share attributable to Innoviva stockholders	$ 2.20	$ 2.37	$ 2.87
Shares used to compute Innoviva basic and diluted net income per share:			
Shares used to compute basic net income per share	65,435	69,644	82,062
Shares used to compute diluted net income per share	86,876	95,248	94,310

See accompanying notes to consolidated financial statements.

INNOVIVA, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(In thousands)

	Year Ended December 31,		
	2023	2022	2021
Net income	$ 179,722	$ 220,262	$ 368,837
Comprehensive income	179,722	220,262	368,837
Comprehensive income attributable to noncontrolling interests	—	6,341	102,983
Comprehensive income attributable to Innoviva stockholders	$ 179,722	$ 213,921	$ 265,854

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated	Treasury Stock		Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Shares	Amount	Interest	Equity
Balance as of January 1, 2021	101,392	$ 1,014	$ 1,260,900	$ (722,002)	—	$ —	$ 67,925	607,837
Distributions to noncontrolling interests	—	—	—	—	—	—	(59,457)	(59,457)
Equity activity of noncontrolling interests in a consolidated variable interest entity	—	—	—	—	—	—	(259)	(259)
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	179	2	1,107	—	—	—	—	1,109
Repurchase of common stock	(32,005)	(320)	—	—	32,005	(393,829)	—	(394,149)
Stock-based compensation	—	—	2,017	—	—	—	—	2,017
Net income	—	—	—	265,854	—	—	102,983	368,837
Balance as of December 31, 2021	69,566	$ 696	$ 1,264,024	$ (456,148)	32,005	$ (393,829)	$ 111,192	$ 525,935
Cumulative adjustment due to adoption of ASU 2020-06	—	—	(65,467)	37,238	—	—	—	(28,229)
Distributions to noncontrolling interests	—				—	—	(69,811)	(69,811)
Recognition of noncontrolling interest upon initial consolidation of Entasis	—	—	—	—	—	—	38,471	38,471
Equity activity of noncontrolling interests in a consolidated variable interest entity					—	—	(2)	(2)
Derecognition of noncontrolling interests upon sale of TRC	—	—	—	78	—	—	(61,304)	(61,226)
Derecognition of noncontrolling interests upon acquisition of Entasis noncontrolling interest	—	—	(14,153)	—	—	—	(28,009)	(42,162)
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	269	2	286	—	—	—	—	288
Capped call options associated with convertible senior notes due 2028	—	—	(16,585)	—	—	—	—	(16,585)
Conversion of convertible subordinated notes due 2023	—	—	3	—	—	—	—	3

Repurchase of common stock	(647)	(6)	(8,497)	—			—	(8,503)
Stock-based compensation	—	—	4,225	—	—	—	3,122	7,347
Net income	—	—	—	213,921	—	—	6,341	220,262
Balance as of December 31, 2022	69,188	$ 692	$ 1,163,836	$ 204,911)	32,005	$ 393,829)	$ —	$ 565,788
Exercise of stock options and issuance of common stock units and stock awards, net of repurchase of shares to satisfy tax withholding	293	3	89	—	—	—	—	92
Repurchase of common stock	(6,174)	(62)	(76,422)	—				(76,484)
Stock-based compensation	—	—	5,837	—	—	—	—	5,837
Net income	—	—	—	179,722	—	—	—	179,722
Balance as of December 31, 2023	63,307	$ 633	$ 1,093,340	$ 25,189)	32,005	$ 393,829)	$ —	$ 674,955

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2023	2022	2021
Cash flows from operating activities			
Net income	$ 179,722	$ 220,262	$ 368,837
Adjustments to reconcile net income to net cash provided by operating activities:			
Deferred income taxes	4,400	25,006	76,432
Amortization of capitalized fees and depreciation of property and equipment	13,921	13,931	13,832
Amortization of acquired intangible assets	21,784	5,581	—
Inventory fair value step-up adjustment included in cost of products sold	27,164	10,023	—
Stock-based compensation	5,837	7,347	2,017
Amortization of debt discount and issuance costs	2,065	2,055	9,136
Changes in fair values of equity method investments, net	(77,392)	161,749	(84,392)
Changes in fair values of equity and long-term investments, net	(11,129)	(8,462)	(4,917)
Loss on extinguishment of debt	—	20,662	—
Net gain on sale of TRC	—	(266,696)	—
Other non-cash items	(517)	3,402	(259)
Changes in operating assets and liabilities:			
Accounts receivable	(5,053)	(3,525)	—
Receivables from collaboration arrangements	(14,949)	13,319	(16,780)
Inventory	(12,004)	280	—
Prepaid expenses	7,929	(21,350)	203
Other assets	(2,965)	(3,341)	—

Accounts payable	3,778	92	(39)
Accrued personnel-related expenses and other accrued liabilities	(1,498)	11,913	(257)
Accrued interest payable	(937)	207	—
Deferred revenue	(817)	(755)	—
Income tax payable	1,725	10,026	—
Net cash provided by operating activities	141,064	201,726	363,813
Cash flows from investing activities			
Purchases of equity method investments	—	(45,000)	(44,000)
Purchases of trading securities	(65,132)	—	(15,905)
Purchases of equity and long-term investments	(1,218)	(13,725)	(6,373)
Purchases of equity investments managed by ISP Fund LP	(31,164)	(60,910)	(190,970)
Purchases of trading security managed by ISP Fund LP	—	(50,000)	—
Sales of equity investments managed by ISP Fund LP	72,500	24,281	21,440
Purchase and sales of other investments managed by ISP Fund LP, net	(41,336)	(23,371)	279,530
Purchases of property and equipment	(411)	(67)	—
Proceeds from sale of ownership interest in TRC, net	—	248,191	—
Cash acquired through the consolidation of Entasis	—	23,070	—
Cash paid for the acquisition of La Jolla, net of cash acquired	—	(159,103)	—
Net cash provided by (used in) investing activities	(66,761)	(56,634)	43,722
Cash flows from financing activities			
Distributions to noncontrolling interests	—	(69,811)	(59,457)
Purchase of Entasis noncontrolling interest	—	(43,910)	—

Repurchase of common stock	(75,728)	(8,503)	(394,149)
Repurchase of shares to satisfy tax withholding	(77)	(82)	(60)
Proceeds from issuances of common stock, net	170	370	1,169
Payment for repurchase of convertible subordinated notes due 2023	(96,204)	(165,131)	—
Purchases of capped call options associated with convertible senior notes due 2028	—	(21,037)	—
Proceeds from issuance of convertible senior notes due 2028, net of issuance costs	—	252,536	—
Net cash used in financing activities	(171,839)	(55,568)	(452,497)
Net increase (decrease) in cash and cash equivalents	(97,536)	89,524	(44,962)
Cash and cash equivalents at beginning of period	291,049	201,525	246,487
Cash and cash equivalents at end of period	$ 193,513	$ 291,049	$ 201,525

	Year Ended December 31,		
	2023	**2022**	**2021**
Supplemental Disclosure of Cash Flow Information:			
Cash paid for interest	$ 11,381	$ 11,736	$ 9,933
Cash paid for income taxes	$ —	$ 53,855	$ —
Supplemental Disclosure of Non-cash Investing and Financing Activities:			
Accrued interest income converted to long-term investments	$ 2,666	$ —	$ —
Adoption of ASU 2020-06	$ —	$ (28,228)	$ —

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, Inc. (and where context requires, together with its subsidiaries referred to as "Innoviva", the "Company", or "we" and other similar pronouns) is a company with a portfolio of royalties and innovative healthcare assets. Our royalty portfolio contains respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/vilanterol, "UMEC/VI"), and up until July 2022, TRELEGY® ELLIPTA® (the combination FF/UMEC/VI). We sold our

15

% ownership interest in Theravance Respiratory Company, LLC ("TRC") on July 20, 2022, and are no longer entitled to receive royalties on sales of TRELEGY® ELLIPTA® products. 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
%.

We expanded our portfolio through the acquisition of Entasis Therapeutics Holdings Inc. ("Entasis") on July 11, 2022 and the acquisition of La Jolla Pharmaceutical Company ("La Jolla") on August 22, 2022. Our commercial and marketed products include GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock, and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults. Our new product, XACDURO® (formerly known as sulbactam-durlobactam or SUL-DUR), was approved by the United States Food and Drug Administration ("FDA") for the treatment of hospital-acquired and ventilator-associated pneumonias caused by *Acinetobacter* in adults on May 23, 2023. We commenced commercial sales of XACDURO® in the third quarter of 2023. Our development pipeline includes zoliflodacin, an investigational treatment for uncomplicated gonorrhea that reported positive data in a pivotal Phase 3 clinical trial on November 1, 2023. As such, we have a wholly owned robust critical care and infectious disease operating platform with a hospital focus anchored by three differentiated products with significant growth potential and a promising drug candidate.

In addition, we own other strategic healthcare assets, such as a large equity stake in Armata Pharmaceuticals, a leader in development of bacteriophages with potential use across a range of infectious and other serious diseases. We also have economic interests in other healthcare companies.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Innoviva, our wholly owned subsidiaries and certain variable interest entities ("VIE") for which we are the primary beneficiary. All intercompany balances and transactions have been eliminated in consolidation. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income (loss) attributable to noncontrolling interest in our consolidated statements of income equal to the percentage of the economic or ownership interest retained in such entity by the respective noncontrolling party.

Presentation Reclassification

Amounts in equity and long-term investments reported in the Company's comparative financial statements have been reclassified to conform to the current year presentation. Certain reclassifications have been made to the consolidated statement of cash flows for the years ended December 31, 2022 and 2021 to conform to the current year's presentation. These reclassifications had no net effect on the net income or net cash flows from operating, investing and financing activities as previously reported.

Factors Affecting Comparability

Our historical financial condition and results of operations for the periods presented may not be comparable, either between periods or going forward due to the factors below and as discussed in Note 5, "Consolidated Entities and Acquisitions".

- Adoption of Accounting Standards Update 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* ("ASU 2020-06") effective January 1, 2022;
- Accounting consolidation of Entasis on February 17, 2022 and purchase of remaining noncontrolling interest in Entasis on July 11, 2022;
- Sale of our

  15
  % ownership interest in TRC on July 20, 2022; and
- Acquisition of La Jolla on August 22, 2022.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Use of Management's Estimates

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ("U.S. 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.

Concentrations of Credit Risk and of Significant Suppliers and Partners

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and equity and long-term investments. Although we deposit our cash with multiple financial institutions, our deposits, at times, may exceed federally insured limits.

We are dependent on third-party manufacturers to supply active pharmaceutical ingredients ("API") and drug products for research and development and commercial programs. These programs could be adversely affected by significant interruption in the supply of API or drug products.

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. 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® and ANORO® ELLIPTA®. 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® and ANORO® ELLIPTA®. Our royalty revenues may fluctuate due to a variety of factors, many of which are outside of our control. Our royalty revenues under the GSK Agreements may not meet our, analysts' or investors' expectations, due to a number of important factors.

We started recognizing revenue from product sales of GIAPREZA® and XERAVA® in 2022 as a result of our acquisition of La Jolla. In the current year, we also started recognizing revenue from product sales from XACDURO®, which was commercially launched in the third quarter of 2023. Hospitals and other healthcare organizations generally purchase our products through a network of specialty distributors. These specialty distributors, which are located in the U.S., are considered our customers for accounting purposes. We do not believe that loss of one of these distributors would significantly impact our ability to distribute our products, as we expect that sales volume would be absorbed by new or remaining distributors.

Three of our customers each account for approximately 31%, 27% and 27%, respectively, of our net product sales for the year ended December 31, 2023. These same customers account for 29%, 19% and 15%, respectively, of our receivables from net product sales, which are included in "Accounts receivables, net" in our consolidated balance sheet as of December 31, 2023. Three of our customers each account for approximately 33%, 29% and 28%, respectively, of our net product sales from the time of our acquisition of La Jolla through December 31, 2022. These same customers account for 23%, 37% and 37%, respectively, of our receivables from net product sales, which are included in "Accounts receivables, net" in our consolidated balance sheet as of December 31, 2022.

Segment Reporting

We operate in a single segment, which is to provide capital return to stockholders by maximizing the potential value of our portfolio of royalties and

innovative healthcare assets. Our Chief Operating Decision Maker ("CODM") is our Chief Executive Officer. The CODM allocates resources and evaluates the performance of Innoviva at the consolidated level using information about our revenues, operating results and other key financial data as needed. Our revenues are generated primarily from our collaborative arrangements and royalty payments from GSK, located in Great Britain. We also generate revenue from net product sales of GIAPREZA®, XERAVA®, and XACDURO®. Refer to Note 3, "Revenue Recognition", for more information on our revenues for the periods presented. Our long-term assets are located within the United States.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Variable Interest Entities

The primary beneficiary of a variable interest entity ("VIE") is required to consolidate the assets and liabilities of the VIE. When we obtain a variable interest in another entity, we assess at the inception of the relationship and upon occurrence of certain significant events whether the entity is a VIE and, if so, whether we are the primary beneficiary of the VIE based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE.

To assess whether we have the power to direct the activities of a VIE that most significantly impact the VIE's economic performance, we consider all the facts and circumstances, including our role in establishing the VIE and our ongoing rights and responsibilities. This assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has power over those activities. In general, the parties that make the most significant decisions affecting the VIE (management and representation on the Board of Directors) and have the right to unilaterally remove those decision-makers are deemed to have the power to direct the activities of a VIE.

To assess whether we have the obligation to absorb losses of the VIE or the right to receive benefits from the VIE that could potentially be significant to the VIE, we consider all of our economic interests that are deemed to be variable interests in the VIE. This assessment requires us to apply judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE.

Business Combination

When we acquire an entity in a business combination, we recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establish the acquisition date as the fair value measurement point. We recognize and measure goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired. Acquisition-related expenses and related restructuring costs are expensed as incurred.

Several valuation methods may be used to determine the fair value of assets acquired and liabilities assumed. For intangible assets, we typically use the income method. This method starts with a forecast of all of the expected future net cash flows for each asset. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income method or other methods include the amount and timing of projected future cash flows, the discount rate selected to measure the risks inherent in the future cash flows and the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry. Determining the useful life of an intangible asset also requires judgment as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives.

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.

Accounts Receivable

Accounts receivable are recorded net of estimates for prompt-pay discounts, chargebacks, returns and rebates. Allowances for prompt-pay discounts and chargebacks are based on contractual terms. We estimate the allowance for credit losses based on existing contractual payment terms, actual payment patterns of customers and individual customer circumstances.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out basis. We periodically analyze inventory levels and write down inventory as cost of products sold when the following occurs: inventory has become obsolete, inventory has a cost basis in excess of its estimated net realizable value, or inventory quantities are in excess of expected product sales.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment

Property and equipment, which consisted of laboratory equipment, computer equipment, software, office furniture and fixtures, and leasehold improvements, were not material as of December 31, 2023 and 2022, respectively.

Property and equipment are stated at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

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

Equity and Long-Term Investments

We invest from time to time in equity and debt securities of private or public companies. If we determine that we have control over these companies under either voting or VIE models, we consolidate 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 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 method investments, net, and changes in fair values of equity and long-term investments, net, within 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 the security without a readily determinable fair value using the measurement alternative method under ASC 321, *Investments – Equity Securities*. This measurement alternative method 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.

We also invest in ISP Fund LP, which investments consist of money market funds and equity and debt securities in the healthcare, pharmaceutical and biotechnology industries. Pursuant to the Partnership Agreement entered in December 2020, we became a limited partner of this partnership, and our contributions are subject to a 36-month lock-up period, which restriction prevents us from having control and access to the contributions and related investments. The lock-up period for a certain portion of our contributions expired in December 2023. Strategic Partners did not elect to make a withdrawal in 2023, thereby extending the lock-up period and withdrawal elections into subsequent years. These investments are classified as long-term investments in the consolidated balance sheets.

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.

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 3or 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.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Financial instruments include cash equivalents, accounts receivable, receivables from collaborative arrangements, accounts payable, and accrued liabilities, equity investments and convertible promissory notes. The carrying values of cash equivalents, receivables from collaborative arrangements, accounts payable, and accrued liabilities approximate their estimated fair values due to the relatively short-term nature of these instruments.

Capitalized Fees Paid

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as capitalized fees paid ("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.

Goodwill and Intangible Assets

Goodwill is recognized as the excess of the purchase consideration of an acquired entity over the fair value assigned to assets acquired and liabilities assumed in a business combination. Goodwill and intangible assets with indefinite useful life are not amortized and are tested for impairment at least annually on the first day of December of each year or more frequently if indicators for potential impairment exist or whenever events or changes in circumstances indicate that the asset's carrying asset amount may not be recoverable. Intangible assets with definite useful lives are amortized on a straight-line basis over their respective remaining useful lives and are tested for impairment only if indicators for potential impairment exist or whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. Significant judgment may be involved in determining if an indicator of impairment has occurred.

Operating Leases

Right-of-use assets represent our right to use an underlying asset over the lease term and include any lease payments made prior to the lease commencement date and are reduced by lease incentives. Lease liabilities represent the present value of the total lease payments over the lease term, calculated using an estimated incremental borrowing rate. Lease expense is recognized on a straight-line basis over the expected lease term.

Revenue Recognition

We apply the guidance on principal versus agent considerations under ASC Topic 606, *Revenue from Contracts with Customers*, to determine the appropriate treatment for the transactions between us and third parties. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which we are considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as product sales.

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 the 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 as a performance obligation is satisfied.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Royalty Revenue

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. The net sales reports provided by our partner are based on its methodology and assumptions to estimate rebates and returns, which it monitors and adjusts regularly in light of contractual and legal obligations, historical trends, past experience and projected market conditions. Our partner may make significant adjustments to its sales based on actual results recorded, which could cause our royalty revenue to fluctuate. We conduct periodic royalty audits to evaluate the information provided by our partner. Royalties are recognized net of amortization of capitalized fees associated with any approval and launch milestone payments made to GSK.

Revenue from Product Sales

Revenue from product sales is recognized when our customers obtain control of the product and is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and rebates. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These items may include:

- Chargebacks: Chargebacks are discounts we provide to distributors in the event that the sales prices to end users are below the distributors' acquisition price. This may occur due to a direct contract with a health system, a group purchasing organization ("GPO") agreement or a sale to a government facility. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to our customers.
- Discounts: We offer customers various forms of incentives and consideration, including prompt-pay and other discounts. We estimate discounts primarily based on contractual terms. These discounts are recorded as a reduction of revenue on delivery to our customers.
- Returns: We offer customers a limited right of return, generally for damaged or expired product. We estimate returns based on an internal analysis, which includes actual experience. The estimates for returns are recorded as a reduction of revenue on delivery to our customers.
- Rebates: We participate in Medicaid rebate programs, which provide assistance to certain low-income patients based on each individual state's guidelines regarding eligibility and services. Under the Medicaid rebate programs, we pay a rebate to each participating state, generally within three months after the quarter in which product was sold. Additionally, we may offer customer incentives and consideration in the form of volume-based or other rebates. The estimates for rebates are recorded as a reduction of revenue on delivery to our customers.

We continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly.

License Revenue

At the inception of a licensing arrangement that includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price. We generally recognize these milestone payments as revenues when they are achieved because there is considerable uncertainty in the research and development processes that trigger receipt of these payments under our agreements. Similarly, we recognize regulatory approval milestone payments as revenues once the product is approved by the applicable regulatory agency.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Research and Development Expenses

Research and development expenses are recognized in the period that services are rendered or goods are received. Research and development expenses consist of salaries and benefits, laboratory supplies, facilities and other overhead costs, research-related manufacturing costs, contract service and clinical-related service costs performed by third party research organizations, research institutions and other outside service providers. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the related goods are delivered or the related services are performed. We also utilize significant judgment and estimates to record accruals for estimated ongoing research costs based on the progress of the studies and progress of research manufacturing activities.

Interest Expense on Deferred Royalty Obligation

Interest expense related to the deferred royalty obligation is recognized over the expected repayment term of the deferred royalty obligation using the effective interest method. The assumptions used in determining the expected repayment term of the deferred royalty obligation require us to make estimates that could impact the effective interest rate. Each reporting period, we estimate the expected repayment term of the deferred royalty obligation based on forecasted net sales of GIAPREZA®. Changes in interest expense resulting from changes in the effective interest rate, if any, are recorded on a prospective basis. Refer to Note 12, “Debt”, for more information.

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. 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.

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 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.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 determine whether the factors underlying the sustainability assertion have changed and whether the amount of the recognized tax benefit is still appropriate.

Related Parties

Transactions with GSK were considered related party transactions up until May 2021, when we completed the share repurchase agreement with GSK to buy back all of its shares of common stock in Innoviva. GSK is no longer considered a related party after the completion of the share repurchase. Transactions with GSK are described in Note 3, "Revenue Recognition and Collaborative Arrangements."

Sarissa Capital owned

11.5

% of our outstanding common stock as of December 31, 2023. Transactions with Sarissa Capital are described in Note 5, "Consolidated Entities and Acquisitions". Sarissa Capital is considered to be a related party because two of its principals are members of our board of directors.

Recently Issued Accounting Pronouncements Not Yet Adopted

In October 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. The amendment modifies the disclosure or presentation requirements for a variety of topics. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280).* This ASU update requires enhanced segment disclosures, primarily related to significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The ASU requires the disclosure of income taxes paid disaggregated by jurisdiction and enhanced disclosures for the entity's effective tax rate reconciliation as well as other income tax related disclosures. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

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") up until its maturity date on January 15, 2023, our convertible senior notes due 2025 (the "2025 Notes"), and our convertible senior notes due 2028 (the "2028 Notes") using the if-converted method.

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 was historically computed using the treasury stock method until the adoption of ASU 2020-06. 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 year ended December 31, 2021.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table shows the computation of basic and diluted net income per share for the years ended December 31, 2023, 2022 and 2021:

(In thousands except per share data)	Year Ended December 31, 2023	2022	2021
Numerator:			
Net income attributable to Innoviva stockholders, basic	$ 179,722	$ 213,921	$ 265,854
Add: interest expense on 2023 Notes, net of tax effect	89	2,439	4,736
Add: interest expense on 2025 Notes, net of tax effect	5,116	4,583	—
Add: interest expense on 2028 Notes, net of tax effect	6,377	4,626	—
Net income attributable to Innoviva stockholders, diluted	$ 191,304	$ 225,569	$ 270,590
Denominator:			
Weighted-average shares used to compute basic net income per share attributable to Innoviva stockholders	65,435	69,644	82,062
Dilutive effect of 2023 Notes	187	6,188	12,189
Dilutive effect of 2025 Notes	11,150	11,150	—
Dilutive effect of 2028 Notes	9,955	8,158	—
Dilutive effect of options and awards granted under equity incentive plan and employee stock purchase plan	149	108	59
Weighted-average shares used to compute diluted net income per share attributable to Innoviva stockholders	86,876	95,248	94,310
Net income per share attributable to Innoviva stockholders			
Basic	$ 2.75	$ 3.07	$ 3.24
Diluted	$ 2.20	$ 2.37	$ 2.87

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 for the periods presented:

(In thousands)	Year Ended December 31, 2023	2022	2021
Outstanding options and awards granted under equity incentive plan and employee stock purchase plan	1,333	648	979

Outstanding stock warrant	591	282	—
Total	1,924	930	979

3. REVENUE RECOGNITION

Net Revenue from Collaboration Arrangement

On July 13, 2022, Innoviva's wholly owned subsidiary, Innoviva TRC Holdings, LLC ("ITH") entered into an equity purchase agreement ("TRC Equity Purchase Agreement") with Royalty Pharma Investments 2019 ICAV ("Royalty Pharma") to sell our ownership interest in TRC. As a result of the sale of our ownership interest in TRC, which was consummated on July 20, 2022, we are no longer entitled to receive

15

% of royalty payments made by GSK stemming from sales of TRELEGY® ELLIPTA®. We retained our royalty rights with respect to RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Year Ended December 31, 2023	2022	2021
Royalties – RELVAR/BREO	$ 208,042	$ 215,034	$ 234,066
Royalties – ANORO	44,627	38,405	44,935
Royalties – TRELEGY[1]	—	72,029	126,688
Total royalties	252,669	325,468	405,689
Less: amortization of capitalized fees paid	(13,823)	(13,823)	(13,823)
Total royalty revenue	$ 238,846	$ 311,645	$ 391,866

[1] The year ended December 31, 2022 represents the period from January 1, 2022 to July 20, 2022, the date of the sale of our ownership interest in TRC.

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, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product. The amortization 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® through July 20, 2022, which royalties were upward tiering and ranged from

6.5

% to

10

%.

Net Product Sales

Net product sales were $

60.6
million, consisting of net sales of GIAPREZA®, XERAVA®, and XACDURO® for $

41.3
million, $

17.3
million, and $

2.0
million, respectively. We derived approximately

91
% and

9
% of our net product sales for the same period from customers located in the U.S. and the rest of the world, respectively.

From the date of acquisition of La Jolla to December 31, 2022, net product sales were $

19.7
million, consisting of net sales of GIAPREZA® and XERAVA® for $

14.2
million and $

5.5
million, respectively. We derived approximately

96
% and

4
% of our net product sales for the same period from customers located in the U.S. and the rest of the world, respectively.

License Revenue

Refer to the out-license agreement with Zai Lab and Everest in Note 4, “License and Collaboration Arrangements”.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. LICENSE AND COLLABORATION ARRANGEMENTS

Out-License Agreements

Zai Lab

Entasis entered into a license and collaboration agreement with Zai Lab (Shanghai) Co., Ltd. ("Zai Lab") (Nasdaq: ZLAB), pursuant to which Zai Lab licensed exclusive rights to durlobactam and SUL-DUR, in the Asia-Pacific region ("the Zai Agreement"). Under the terms of the Zai Agreement, Zai Lab will fund most of the registrational clinical trial costs in China for SUL-DUR, with the exception of Phase 3 patient drug supply of licensed products. Zai Lab will conduct development activities and plan and obtain regulatory approval in a specified number of countries in the Asia-Pacific region beyond China after receipt of regulatory approval of a licensed product in China. Zai Lab is also solely responsible for commercializing licensed products in the Asia-Pacific region and will commercialize licensed products for which it has obtained regulatory approval. We are obligated to supply Zai Lab with the licensed products for clinical development and, if the licensed product is approved, for commercial use for a certain period unless Zai Lab notifies otherwise. Zai Lab may take over manufacturing responsibilities for its own commercialization activities within a specified time period following the effective date of the Zai Agreement.

We are eligible to receive up to an aggregate of $

91.0

million in research and development support payments and development, regulatory and sales milestone payments related to SUL-DUR, imipenem and other combinations with the licensed products. Zai Lab will pay us a tiered royalty equal to from a high-single digit to low-double digit percentage based on annual net sales of licensed products in the territory, subject to specified reductions for the market entry of competing products, loss of patent coverage of licensed products and for payments owed to third parties for additional rights necessary to commercialize licensed products in the territory. Payments received for research support and reimbursable clinical trial costs are recorded as a reduction to research and development expense during the period in which the qualifying expenses are incurred. Such amounts recorded for the year ended December 31, 2023 and from the date of acquisition of Entasis to December 31, 2022 are not material. Following the approval of XACDURO® by the FDA in May 2023, we recognized $

3.0

million in license revenue for the year ended December 31, 2023.

GARDP

Entasis entered into a collaboration agreement with the Global Antibiotic Research and Development Partnership ("GARDP") for the development, manufacture and commercialization of the product candidate zoliflodacin in certain countries ("the GARDP Collaboration Agreement"). Under the terms of the GARDP Collaboration Agreement, GARDP will use commercially reasonable endeavors to perform and fully fund the Phase 3 registrational trial, including the manufacture and supply of the product candidate containing zoliflodacin, in uncomplicated gonorrhea. We recorded reimbursements from GARDP under this agreement as reduction to research and development expense. Relevant amounts for the year ended December 31, 2023 and from the date of acquisition of Entasis to December 31, 2022 are not material.

In addition, under the GARDP Collaboration Agreement, GARDP was granted a worldwide, fully paid, exclusive and royalty-free license, with the right to sublicense, to use our zoliflodacin technology in connection with GARDP's development, manufacture and commercialization of zoliflodacin in low-income and specified middle-income countries. We retained commercial rights in all other countries worldwide, including the major markets in North America, Europe and Asia-Pacific. We also retained the right to use and grant licenses to our zoliflodacin technology to perform our obligations under the GARDP Collaboration Agreement and for any purpose other than gonorrhea or community-acquired indications. If we believe that the results of the Phase 3 registrational trial of zoliflodacin would be supportive of an application for marketing approval, we are obligated to use our best efforts to file an application for marketing approval with the FDA within six months of the completion of the trial and to use commercially reasonable endeavors to file an application for marketing approval with the European Medicines Agency ("EMA"). Each party is responsible for using commercially reasonable efforts to obtain marketing authorizations for the product candidate in their respective territories.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

PAION AG

Pursuant to the PAION AG and PAION Deutschland GmbH (together and individually "PAION") License, La Jolla granted PAION an exclusive license to commercialize GIAPREZA® and XERAVA® in the European Economic Area, the United Kingdom and Switzerland (collectively, the "PAION Territory"). We are entitled to receive potential commercial milestone payments of up to $

109.5

million and double-digit tiered royalty payments. Royalties payable in a given jurisdiction under the PAION License will be subject to reduction on account of generic competition and after patent expiration in that jurisdiction. Pursuant to the PAION License, PAION will be solely responsible for the future development and commercialization of GIAPREZA® and XERAVA® in the PAION Territory. PAION is required to use commercially reasonable efforts to commercialize GIAPREZA® and XERAVA® in the PAION Territory. We have not recognized any revenue from PAION related to commercial milestones from the date of acquisition of La Jolla to December 31, 2023. Royalty revenue recognized under this agreement for the year ended December 31, 2023 and from the date of acquisition of La Jolla to December 31, 2022 are not material.

La Jolla also entered into the PAION commercial supply agreement (the "PAION Supply Agreement") whereby La Jolla will supply PAION a minimum quantity of GIAPREZA® and XERAVA® through July 13, 2024. The PAION supply agreement will automatically renew until the earlier of July 13, 2027, or until a new supply agreement is executed. During the initial term of the supply agreement, we will be reimbursed for direct and certain indirect manufacturing costs at cost. We recognized $

1.3

million in cost reimbursements under this agreement for the year ended December 31, 2023. Amounts recognized under this agreement from the date of acquisition of La Jolla to December 31, 2022 were not material.

PAION AG and PAION Deutschland GmbH filed for insolvency in Germany on October 27, 2023 and the insolvency proceedings were opened on January 1, 2024. PAION announced on December 22, 2023 that it concluded negotiations with Humanwell Healthcare Group and entered into an agreement on the sale of the essential business operations of PAION AG and PAION Deutschland GmbH with the approval of the insolvency administrator in both procedures. La Jolla did not oppose the sale and is in discussions with the acquirer regarding the continued business relationship.

Everest Medicines Limited

Pursuant to the Everest Medicines Limited ("Everest") License, La Jolla granted Everest an exclusive license to develop and commercialize XERAVA® for the treatment of complicated intra-abdominal infections ("cIAI") and other indications in mainland China, Taiwan, Hong Kong, Macau, South Korea, Singapore, the Malaysian Federation, the Kingdom of Thailand, the Republic of Indonesia, the Socialist Republic of Vietnam and the Republic of the Philippines (collectively, the "Everest Territory"). Under the Everest License, we recognized $

8.0

million in license revenue for the year ended December 31, 2023 as a result of an achievement of a regulatory milestone during the period. We are eligible to receive additional sales milestone payments of up to an aggregate of $

20.0

million.

We are also entitled to receive tiered royalties from Everest at percentages in the low double digits on sales, if any, in the Everest Territory of products containing eravacycline. Royalties are payable with respect to each jurisdiction in the Everest Territory until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in the Everest Territory; (ii) expiration of marketing or regulatory exclusivity in such jurisdiction in the Everest Territory; or (iii) 10 years after the first commercial sale of a product in such jurisdiction in the Everest Territory. Royalty revenue recognized under this agreement for the year ended December 31, 2023 was $

1.4

million. Royalty revenue recognized from the date of acquisition of La Jolla to December 31, 2022 is not material.

La Jolla also entered into the Everest commercial supply agreement (the "Everest Supply Agreement") whereby La Jolla will supply Everest a minimum quantity of XERAVA® through December 31, 2023 and will transfer to Everest certain XERAVA®-related manufacturing know-how. We were eligible to be reimbursed for direct and certain indirect manufacturing costs at

110

% of cost through December 31, 2023. We recognized $

2.4

million and $

0.8

million in revenue under this agreement for the year ended December 31, 2023 and from the acquisition of La Jolla to December 31, 2022, respectively.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In-License Agreements

George Washington University

Pursuant to the George Washington University ("GW") License, GW exclusively licensed to La Jolla certain intellectual property rights relating to GIAPREZA®, including the exclusive rights to certain issued patents and patent applications covering GIAPREZA®. Under the GW License, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell GIAPREZA®. We are obligated to pay a

6

% royalty on net sales of GIAPREZA® and

15

% on payments received from sublicensees. The obligation to pay royalties under this agreement extends through the last-to-expire patent covering GIAPREZA®. We recognized $

2.5

million for the year ended December 31, 2023 under this agreement. Amounts recognized from the date of acquisition of La Jolla to December 31, 2022 were not material.

Harvard University

Pursuant to the Harvard University ("Harvard") License, Harvard exclusively licensed to La Jolla certain intellectual property rights relating to tetracycline-based products, including XERAVA®, including the exclusive rights to certain issued patents and patent applications covering such products. Under the Harvard License, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell tetracycline-based products, including XERAVA®. For each product covered by the Harvard License, we are obligated to make certain payments for the following: (i) up to approximately $

15.1

million upon the achievement of certain clinical development and regulatory milestones; (ii) a

5

% royalty on direct U.S. net sales of XERAVA®; (iii) a single-digit tiered royalty on direct ex-U.S. net sales of XERAVA®, starting at a minimum royalty rate of

4.5

%, with step-ups to a maximum royalty of

7.5

% based on the achievement of annual net product sales thresholds; and (iv)

20

% on payments received from sublicensees. The obligation to pay royalties under this agreement extends through the last-to-expire patent covering tetracycline-based products, including XERAVA®. For the year ended December 31, 2023, we recognized $

1.2

million as cost of license revenue under this agreement as a result of the license revenue we earned under the out-licensing agreement with Everest for the same period. From the date of acquisition of La Jolla to December 31, 2022, amounts recognized under this agreement were not material.

Paratek Pharmaceuticals, Inc.

Pursuant to the Paratek Pharmaceuticals, Inc. ("Paratek") License, Paratek non-exclusively licensed to La Jolla certain intellectual property rights relating to XERAVA®, including non-exclusive rights to certain issued patents and patent applications covering XERAVA®. We are obligated to pay Paratek a

2.25

% royalty based on direct U.S. net sales of XERAVA®. Our obligation to pay royalties with respect to the licensed product is retroactive to the date of the first commercial sale of XERAVA® and shall continue until there are no longer any valid claims of the Paratek patents, which expired in October 2023 . For the year ended December 31, 2023 and from the date of acquisition of La Jolla to December 31, 2022, amounts recognized under this agreement were not material.

Business Transfer and Subscription Agreement with AstraZeneca

Entasis entered into a Business Transfer and Subscription Agreement with AstraZeneca, AstraZeneca UK Limited and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca") (the "AstraZeneca Agreement") in 2015, which was amended and restated through 2018, pursuant to which Entasis obtained, among other things, worldwide rights to durlobactam and zoliflodacin. Under the AstraZeneca Agreement, we are obligated to pay AstraZeneca a one-time milestone payment of $

5.0

million within three months of achieving a specified cumulative net sales milestone for durlobactam. We are also obligated to pay AstraZeneca a one-time milestone payment of $

10.0

million within two years of achieving the first commercial sale of zoliflodacin. Additionally, we are obligated to pay AstraZeneca tiered, single-digit royalties on the annual worldwide net sales of durlobactam and, the lesser of tiered, single-digit royalties on the worldwide annual net sales of zoliflodacin and a specified share of the royalties we receive from sublicensees of zoliflodacin. Royalties on sales of zoliflodacin do not include sales by GARDP in low-income and specified middle-income countries as discussed above. Our obligation to make these royalty payments expires with respect to each product on a country-by-country basis upon the later of (i) the 10-year anniversary of the first commercial sale of a product in each such country or (ii)

when the last patent right covering a product expires in each such country.

Royalty expense on durlobactam arising from our net sales of XACDURO® for the year ended December 31, 2023 was immaterial.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. CONSOLIDATED ENTITIES AND ACQUISITIONS

Consolidated Entities

Theravance Respiratory Company, LLC

Up until July 20, 2022, we consolidated TRC under the VIE model as we determined that TRC was a VIE and we were the primary beneficiary of the entity because we had the power to direct the economically significant activities of TRC and the obligation to absorb losses of, or the right to receive benefits from, TRC. We held

15

% ownership interest of TRC. The primary source of revenue for TRC is the royalties generated from the net sales of TRELEGY® ELLIPTA® by GSK.

As discussed in Note 3, “Revenue Recognition”, on July 13, 2022, ITH entered into the TRC Equity Purchase Agreement to sell our ownership interest in TRC. Upon the closing of the transaction on July 20, 2022, we received $

277.5

million in cash from Royalty Pharma. We are also entitled to receive up to $

50.0

million in contingent sales-based milestone payments in the future. In connection with the closing of the transaction, we also received our portion of TRC’s remaining cash balance of $

4.4

million from Royalty Pharma rather than through a cash distribution from TRC.

Prior to the closing of the transaction and as part of the agreement, TRC distributed its ownership interests and investments in InCarda Therapeutics (“InCarda”), Inc., ImaginAb, Inc. (“ImaginAb”), Gate Neurosciences (“Gate”), Inc. and Nanolive SA (“Nanolive”), which had a total carrying value of $

39.4

million, to ITH. We accounted for the transaction similar to an upstream sale between a parent and a VIE under ASC 810-10. As such, ITH recorded the transferred investments at their respective carrying values and no gain or loss was recognized in the consolidated statement of income.

The summarized financial information of TRC for the relevant periods through the sale date in 2022 are presented as follows:

Income statements

(In thousands)	Year Ended December 31, 2022[1]	2021
Royalty revenue	$ 72,029	$ 126,688
Operating expenses	(332)	(3,956)
Income from operations	71,697	122,732
Other income, net	10	—
Realized loss	(39,386)	—
Income tax expense, net	1	—
Changes in fair values of equity and long-term investments	(8,884)	(1,541)
Net income	$ 23,438	$ 121,191

[1] The year ended December 31, 2022 represents the period from January 1, 2022 to July 20, 2022, the date of the sale of our ownership interest in TRC.

ISP Fund LP

In December 2020, Innoviva Strategic Partners LLC, our wholly owned subsidiary (“Strategic Partners”), contributed $

300.0

million to ISP Fund LP (the “Partnership”) for investing in “long” positions in the healthcare, pharmaceutical and biotechnology sectors and became a limited partner. The general partner of the Partnership (“General Partner”) is an affiliate of Sarissa Capital.

The Partnership Agreement provides for Sarissa Capital to receive management fees 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 an annual performance fee based on the Net Profits of the Partnership during the annual measurement period.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. The lock-up period for the initial contribution of $

190.0

million, which excludes the amount discussed below, expired in December 2023. Strategic Partners did not elect to make a withdrawal in 2023, thereby extending the lock-up period and withdrawal elections into subsequent years.

In May 2021, Strategic Partners received a distribution of $

110.0

million from the Partnership to provide funding to Innoviva for a strategic repurchase of shares held by GSK. On March 30, 2022, Strategic Partners made an additional capital contribution of $

110.0

million to the Partnership pursuant to the letter agreement entered into between Strategic Partners, the Partnership and Sarissa Capital Fund GP LP on May 20, 2021. The capital contribution is subject to a 36-month lock up period from the contribution date.

We consolidate ISP Fund LP under the VIE model as we have determined that ISP Fund LP is a VIE and we are the primary beneficiary of the entity via our related party relationships with Sarissa Capital entities. Our maximum exposure to loss is equal to the amount we invested in the entity.

ISP Fund LP is determined to be an investment company under ASC 946, *Financial Services – Investment Companies*, as it meets all fundamental characteristics of an investment company, and its activities are consistent with those of an investment company. Since ISP Fund LP is subject to investment company industry specific guidance, we have retained the industry-specific guidance applied by the Partnership. In addition, as our investment in the Partnership is a passive investment for the Company and is not part of our main operations, the investments are presented as part of “Equity and long-term investments” in our consolidated balance sheets. We report in our consolidated statements of income any investment gains and losses by the Partnership as part of “Changes in fair value of equity and long-term investments, net”, any interest and dividend income as part of “Interest and dividend income” and any investment expenses as part of “Other expense, net”.

As of December 31, 2023, we continued to hold

100

% of the economic interest of Partnership. As of December 31, 2023 and 2022, total assets of the Partnership were $

311.8

million and $

320.6

million, respectively, of which the majority was attributable to equity and long-term investments. As of December 31, 2023 and 2022, total liabilities of the Partnership were $

0.1

million and $

1.6

million, respectively. The Partnership’s assets can only be used to settle its own obligations. During the year ended December 31, 2023, the Partnership incurred $

4.3

million in net investment-related expenses, generated $

6.3

million interest income, recorded $

2.4

million in net realized losses and $

6.7

million in net unrealized losses as changes in fair values of equity and long-term investments, net, in the consolidated statement of income. During the year ended December 31, 2022, the Partnership incurred $

5.2

million in net investment-related expenses, generated $

2.0

million interest income, recorded $

6.8

million in net realized gains and $

9.9

million in net unrealized losses as changes in fair values of equity and long-term investments, net, in the consolidated statement of income. During the year ended December 31, 2021, the Partnership incurred $

3.6

million in net investment-related expense, generated $

1.8

million interest and dividend income, and recorded net $

10.5
million realized gains and net $

2.4
million unrealized losses as changes in fair values of equity and long-term investments, net, in the consolidated statement of income. We account for the long-term investments held by ISP Fund LP as of December 31, 2023 and 2022 as equity investments measured at fair value and the investment in convertible notes as of December 31, 2022 as trading security.

Acquisitions

Entasis Therapeutics Holdings Inc.

We started investing in Entasis in 2020 as part of our capital allocation strategy of deploying cash generated from royalty income and investing in different life sciences companies. Entasis at the time was an advanced, late clinical-stage biopharmaceutical company focused on the discovery and development of novel antibacterial products. Effective in June 2020, after certain conditions were met with respect to the sales of Entasis equity shares, Innoviva had the right to designate

two
members to Entasis' board. Our investment in Entasis consisted of shares of common stock and warrants to purchase shares of Entasis common stock.

The fair value of Entasis' common stock was measured based on its closing market price at each balance sheet date. We used the Black-Scholes-Merton pricing model to estimate the fair value of the warrants.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On February 17, 2022, Innoviva Strategic Opportunities, LLC ("ISO") entered into a securities purchase agreement with Entasis pursuant to which ISO purchased a convertible promissory note for a total purchase price of $ 15.0 million. The note bore an annual interest rate of 0.59% and was due to mature and become payable on August 18, 2022 unless it was converted at a conversion price of $ 1.48 before the maturity date. With this financing, we determined that we had both (i) the power to direct the economically significant activities of Entasis and (ii) the obligation to absorb the losses, or the right to receive the benefits, that could potentially be significant to Entasis and therefore, we were the primary beneficiary of Entasis. Accordingly, we consolidated Entasis' financial position and results of operations effective on February 17, 2022. Our equity ownership interest remained at 59.9% as of February 17, 2022, and the fair values of our holdings of Entasis common stock and warrants were remeasured and estimated at $ 64.5 million and $ 31.4 million, respectively.

The remeasurement resulted in a $ 7.8 million loss in the first quarter of 2022 which was included in changes in fair values of equity method investments, net, in the consolidated statement of income for the year ended December 31, 2022.

We completed our acquisition of Entasis' minority interest on July 11, 2022.

No payments were made toward the convertible promissory note through the date of acquisition of Entasis. In connection with the acquisition, all of the Entasis warrants were replaced with Innoviva warrants (the "Replacement Warrants") of equivalent value and bearing the same terms. The Replacement Warrants are classified as equity.

We recognized the difference between the acquisition price and the carrying value of the acquired minority interest on July 11, 2022 in our additional paid-in capital.

The fair values assigned to assets acquired and liabilities assumed as of February 17, 2022 were based on management's best estimates and assumptions. After the acquisition in July 2022, we adjusted the purchase price allocation based on new and additional information related to product sales forecast provided by Entasis and deferred tax liabilities.

During the year ended December 31, 2022, we recorded measurement period adjustments of $ 4.7 million decrease in goodwill, primarily related to a decrease in estimated purchase price of $ 1.4 million, an increase in noncontrolling interests of $ 1.7 million, and an increase in intangible assets of $ 2.5 million. The cumulative impact of the measurement period adjustments included in the consolidated net income for the year ended December 31, 2022 was not material.

In February 2023, we recorded a measurement period adjustment of $ 1.2 million increase in goodwill, primarily related to a decrease in intangible assets of $ 0.8 million and an increase in deferred tax liabilities of $ 0.4 million. The measurement period adjustment did not impact the consolidated net income for the year ended December 31, 2023.

The following table represents the adjusted fair values of the assets acquired and liabilities assumed by us in the transaction:

(In thousands)	**February 17, 2022**
Cash and cash equivalents	$ 23,070

Prepaid expenses	5,554
Other current assets	1,959
Property and equipment, net	185
Right-of-use assets	959
Goodwill	11,493
Intangible assets	106,700
Other assets	302
Total assets acquired	$ 150,222
Accounts payable	$ 1,583
Accrued personnel-related expenses	1,058
Other accrued liabilities	5,096
Deferred tax liabilities	7,769
Total liabilities assumed	$ 15,506
Total assets acquired, net	$ 134,716

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The goodwill arising from the acquisition of Entasis is primarily attributable to Entasis' assembled workforce and the value associated with growing our business more efficiently. The goodwill from this acquisition is not expected to be deductible for tax purposes.

Refer to Note 8, "Goodwill and Intangible Assets", for more discussion on the intangible assets recognized as part of this acquisition.

As a result of the consolidation, we recognized a non-controlling interest of $

38.5
million as of February 17, 2022. Our consolidated net income for the year ended December 31, 2022 included the net loss attributable to noncontrolling interest since the consolidation date until the date of acquisition of $

13.6
million.

La Jolla Pharmaceutical Company

On August 22, 2022, ISO acquired La Jolla for a total consideration of $

206.6
million. ISO acquired La Jolla at a price of $

6.23
per share. La Jolla is dedicated to the commercialization of innovative therapies that improve outcomes in patients suffering from life-threatening diseases. La Jolla brought to Innoviva an established product portfolio, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections (cIAIs). We incurred approximately $

5.3
million in acquisition-related costs in connection with this acquisition during the year ended December 31, 2022.

The fair values assigned to assets acquired and liabilities assumed as of August 22, 2022 were based on management's best estimates and assumptions.

During the year ended December 31, 2022, we recorded measurement period adjustments of $

3.7
million increase in goodwill, primarily related to a decrease in inventory and intangible assets of $

7.7
million and $

1.5
million, respectively, and an increase in deferred tax liabilities of $

2.6
million, partially offset by a decrease in other long-term liabilities of $

8.3
million. The cumulative impact of the measurement period adjustments included in the consolidated net income for the year ended December 31, 2022 was not material.

In June 2023, we recorded a measurement period adjustment of $

13.1
million decrease in goodwill, primarily related to an increase in deferred tax assets of $

10.5
million and a decrease in deferred tax liabilities of $

2.6
million. In August 2023, we recorded a measurement period adjustment of $

3.0
million increase in goodwill, primarily related to a decrease in deferred tax assets of $

2.4
million and an increase in deferred tax liabilities of $

0.6
million. The cumulative impact of the measurement period adjustments included did not impact the consolidated net income for the year ended December 31, 2023.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table represents the adjusted fair values of assets acquired and liabilities assumed by us in the transaction:

(In thousands)	August 22, 2022
Cash and cash equivalents	$ 47,415
Short-term marketable securities	471
Accounts receivable	5,876
Inventory	66,200
Prepaid expenses	1,261
Other current assets	907
Property and equipment, net	13
Right-of-use assets	226
Goodwill	6,411
Intangible assets	151,000
Deferred tax assets	7,461
Other assets	710
Total assets acquired	$ 287,951
Accounts payable	$ 1,237
Deferred revenue	2,849
Other accrued liabilities	11,362
Other long-term liabilities	65,944

Total liabilities assumed	$ 81,392
Total assets acquired, net	$ 206,559

The goodwill arising from the acquisition of La Jolla is primarily attributable to La Jolla's assembled workforce and the value associated with leveraging the workforce to develop and commercialize new drug products in the future and growing our business more efficiently. The goodwill from this acquisition is not expected to be deductible for tax purposes.

Refer to Note 8, "Goodwill and Intangible Assets", for more discussion on the intangible assets recognized as part of this acquisition.

Pro Forma Financial Information

The following table presents certain unaudited pro-forma financial information for the years ended December 31, 2022 and 2021 as if the consolidation of Entasis and La Jolla occurred on January 1, 2021. The unaudited pro forma financial information is presented for informational purposes only, and is not indicative of the results of operations that would have been achieved if the acquisitions had taken place on January 1, 2021, or of results that may occur in the future. The unaudited pro forma financial information combines the historical results of the Entasis and La Jolla with the Company's consolidated historical results and includes certain adjustments including, but not limited to, fair value adjustments to equity investments in Entasis' common stock and warrants, fair value adjustments to inventory, amortization of intangible assets, and interest expense on deferred royalty obligations and acquisition-related costs.

	Year Ended December 31,	
(In thousands)	**2022**	**2021**
Revenue	$ 357,880	$ 435,398
Net income	$ 204,987	$ 281,719
Net income attributable to Innoviva stockholders	$ 214,390	$ 197,535

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. EQUITY AND LONG-TERM INVESTMENTS AND FAIR VALUE MEASUREMENTS

Equity and Other Investments in Armata

During the first quarter of 2020, Innoviva acquired

8,710,800
shares of common stock as well as warrants to purchase

8,710,800
additional shares of common stock of Armata Pharmaceuticals, Inc. (“Armata”) for approximately $

25.0
million in cash. Armata is a clinical stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections.

During the first quarter of 2021, ISO entered into a securities purchase agreement with Armata to acquire

6,153,847
shares of Armata common stock and warrants to purchase

6,153,847
additional shares of Armata common stock for approximately $

20.0
million. Armata also entered into a voting agreement with the Company and ISO, pursuant to which the Company and ISO agreed not to vote or take any action by written consent with respect to any common shares held by the Company and ISO that represent, in the aggregate, more than

49.5
% of the total number of shares of Armata’s common stock for voting on the matters related to election or removal of Armata’s board members. The voting agreement will expire the earlier of the second anniversary of the agreement effective date and approval by the FDA of any of Armata’s product candidates for marketing and commercial distribution. During the fourth quarter of 2021, ISO also purchased an additional

1,212,122
shares of Armata common stock for approximately $

4.0
million.

On February 9, 2022, ISO entered into a securities purchase agreement with Armata to acquire

9,000,000
shares of Armata common stock and warrants to purchase

4,500,000
additional shares of common stock with an exercise price of $

5.00
per share for $

45.0
million. The investment closed in

two
tranches on February 9, 2022 and March 31, 2022. The investment is intended to aid Armata in advancing its clinical pipeline and strengthening its bacteriophage platform. On February 9, 2022, Armata also entered a second amended and restated voting agreement with the Company and ISO, pursuant to which the Company and ISO agreed not to vote or take any action by written consent with respect to any common shares held by the Company and ISO that represent, in the aggregate, more than

49.5
% of the total number of shares of Armata’s common stock for voting on the matters related to election or removal of Armata’s board members or amend the bylaws of Armata to reduce the maximum number of directors or set the number of directors who may serve on the board of Armata. The voting agreement will expire the earlier of the second anniversary of the agreement effective date and approval by the FDA of any of Armata’s product candidates for marketing and commercial distribution. In addition, as of February 9, 2022, Armata entered into an amended and restated investor rights agreement with the Company and ISO, pursuant to which for as long as the Company and ISO hold at least

12.5
% of the outstanding shares of Armata’s common stock on a fully-diluted, the Company and ISO shall have the right to designate two directors to Armata’s board of directors, and for so long as the Company and ISO hold at least

8
%, but less than

12.5
%, of the outstanding shares of Armata’s common stock on a fully-diluted basis, the Company and ISO shall have the right to designate one director to Armata’s board of directors, subject to certain conditions and qualifications set forth in the amended and restated investor rights agreement. On July 10, 2023, Armata entered into an amendment to the amended and restated investor rights agreement with the Company and ISO, pursuant to which the Company and ISO agreed that the voting agreement will expire on the earlier of the fifth anniversary of the original agreement's effective date,

January 26, 2021, or the approval by the FDA of any of Armata’s product candidates for marketing and commercial distribution. As of December 31, 2023,

three

of the eight members of Armata’s board of directors are also members of the board of directors of Innoviva. As of December 31, 2023 and 2022, we owned approximately

69.4

% of Armata’s common stock.

On January 10, 2023, we entered into a Secured Convertible Credit Agreement (the “Credit Agreement”) with Armata, under which we invested in a one-year convertible note (the “Armata Convertible Note”) in an aggregate amount of $

30.0

million at an interest rate of

8.0

% per annum. Pursuant to the Credit Agreement, the balance on the Armata Convertible Note, including all accrued and unpaid interest thereon, will convert into shares of Armata's common stock upon the occurrence of a qualified financing, as defined in the Credit Agreement. Any portion of the balance on the Armata Convertible Note, including all accrued and unpaid interest thereon, may also be converted into shares of Armata's common stock at our option once a registration statement covering the resale of such securities has been declared effective by the SEC. The Armata Convertible Note is secured by substantially all of the assets of Armata and its domestic and foreign material subsidiaries. On July 10, 2023, ISO and Armata executed an amendment to the Armata Convertible Note extending the maturity date from January 10, 2024 to January 10, 2025.

On July 10, 2023, ISO and Armata entered into a Credit and Security Agreement (the “Credit and Security Agreement"), under which we extended a term loan to Armata (the “Armata Term Loan”) in an aggregate amount of $

25.0

million. The Armata Term Loan is subject to an interest rate of

14

% per annum and is due to mature on January 10, 2025 . The Credit and Security Agreement is secured by substantially all of the assets of Armata and its domestic and foreign material subsidiaries.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The investments in Armata's common stock and warrants provide Innoviva and ISO the ability to have significant influence, but not control over Armata's operations. Armata's business and affairs are managed under the direction of its board of directors, which Innoviva and ISO do not control. Based on our evaluation, we determined that Armata is a VIE, but Innoviva and ISO are not the primary beneficiaries of the VIE. We have not provided financial or other support that we were not previously contractually required to provide during the periods presented. Our maximum exposure to loss is equal to the amount we invested in the entity.

We account for Armata's common stock and warrants under the equity method using the fair value option. The fair value of Armata's common stock is measured based on its closing market price. The warrants purchased in 2020, 2021 and 2022 have an exercise price of $

2.87
, $

3.25
and $

5.00
per share, respectively. All 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: 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. We account for the Armata Convertible Note as a trading security, measured at fair value using a Monte Carlo simulation model with the probability of certain qualified events and the assumptions of risk-free rate, volatility of stock price and timing of certain qualified events. We account for the Armata Term Loan as a trading security, measured at fair value using an income approach based on the discounted value of expected future cash flows.

As of December 31, 2023, the fair values of our holdings of Armata common stock, warrants, the Armata Convertible Note and the Armata Term Loan were estimated at $

81.2
million, $

35.3
million, $

51.9
million and $

27.0
million, respectively. As of December 31, 2022 the fair values of our holdings of Armata common stock and warrants were estimated at $

31.1
million and $

8.1
million, respectively.

For the Armata common stock and warrants, we recorded $

77.4
million unrealized gains, $

152.5
million unrealized losses and $

78.7
million unrealized gains as changes in fair values of equity method investments, net, in the consolidated statements of income for the years ended December 31, 2023, 2022 and 2021, respectively. For the Armata Convertible Note and Term Loan, we recorded $

21.8
million and $

2.0
million unrealized gain, respectively, as changes in fair values of equity and long-term investments, net, in the consolidated statement of income for year ended December 31, 2023.

The summarized financial information, including the portion we do not own, is presented for Armata on a one quarter lag as follows:

Balance Sheet Information

	September 30,	
(In thousands)	**2023**	**2022**
Current assets		
	$ 36,585	$ 33,245

Noncurrent assets		
	$ 76,176	$ 59,636
Current liabilities		
	$ 21,884	$ 7,004
Noncurrent liabilities		
	$ 103,263	$ 40,300

Income Statement Information

(In thousands)	Twelve Months Ended September 30, 2023	2022	2021
Revenue			
	$ 4,052	$ 5,446	$ 3,989
Loss from operations	$ (41,639)	$ (32,666)	$ (24,227)
Net loss	$ (59,512)	$ (32,650)	$ (23,732)

Equity Method Investment in Entasis

Prior to the consolidation of Entasis' financial position and results of operations in February 2022, we accounted for Entasis as an equity method investment. Refer to Note 5, "Consolidated Entities and Acquisitions", for more information.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The summarized financial information, including the portion we did not own, is presented for Entasis on a one quarter lag regardless of the date of our investments as follows:

Income Statement Information

(In thousands)	Twelve Months Ended September 30, 2021
Loss from operations	$ (52,323)
Net loss	$ (125,413)

Equity Investment in InCarda

During the third quarter of 2020, TRC purchased 20,469,432 shares of Series C preferred stock and a warrant to purchase 5,117,358 additional shares of Series C preferred stock of InCarda Therapeutics, Inc. (“InCarda”) (the “InCarda 2020 Warrant”) for $ 15.8 million, which included $ 0.8 million of transaction costs. 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), InCarda’s lead program, for the treatment of a recent-onset episode of paroxysmal atrial fibrillation. On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to Innoviva’s wholly-owned subsidiary, Innoviva TRC Holdings, LLC (“ITH”) all of TRC’s ownership interests and investments in InCarda. ITH has the right to designate one member to InCarda’s board of directors. As of December 31, 2023, no ITH designee is serving on InCarda’s six -member board. We did not exercise the InCarda 2020 Warrant which expired in March 2023 and wrote off its carrying value of $ 0.1 million during 2023.

On March 9, 2022, TRC entered into a Note and Warrant Purchase Agreement (the “InCarda Agreement”) with InCarda to acquire a convertible promissory note (the “InCarda Convertible Note”) and warrants (the “InCarda 2022 Warrant”) for $ 0.7 million. The InCarda 2022 Warrant expires on March 9, 2027 and is measured at fair value.

On June 15, 2022, the principal amount and the accrued interest of the InCarda Convertible Note were converted into equity securities. In addition, TRC participated in InCarda’s Series D preferred stock financing by investing $ 2.3 million. In connection with the new round of financing, InCarda recapitalized its equity structure resulting in TRC owning 4,093,886 shares of InCarda’s common stock, 37,350 shares of its Series A-1 preferred stock, 20,469,432 shares of its Series C preferred stock, 8,771,780 shares of its Series D-1 preferred stock, 3,369,802 shares of its Series D-2 preferred stock, a warrant to purchase 5,117,358 shares of its Series C preferred stock at $ 0.73 per share and a warrant to purchase 2,490,033 shares of its Series D-1 preferred stock at $

0.20
per share.

As of December 31, 2023 and 2022, we held

8.1
% and

9.0
% of InCarda equity ownership, respectively. Our investment in InCarda does not provide us with the ability to control or have significant influence over InCarda's operations. Based on our evaluation, we determined that InCarda is a VIE, but we are not the primary beneficiary of the VIE. We have not provided financial or other support that we were not previously contractually required to provide during the periods presented. Our maximum exposure to loss is equal to the amount we invested in the entity.

We account for our investments in InCarda under 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. Due to InCarda's equity recapitalization in the second quarter of 2022, TRC reassessed the value of its investments in InCarda using the Option Pricing Model Backsolve valuation methodology. Key assumptions used in the valuation model included an expected holding period of two years , a risk free interest rate of

3.2
%, a dividend yield of

0.0
% and an estimated volatility of

122.0
%. The estimated volatility was calculated based on the historical volatility of a selected peer group of public companies comparable to InCarda. We recognized an impairment charge of $

9.0
million during the second quarter of 2022.

Due to certain changes in InCarda's business operations during the second quarter of 2023, ITH reassessed the value of its investments in InCarda using the Option Pricing Model methodology. Key assumptions used in the valuation model included an expected holding period of two years , a risk-free interest rate of

4.9
%, a dividend yield of

0.0
% and an estimated volatility of

114.2
%. The estimated volatility was calculated based on the historical volatility of a selected peer group of public companies comparable to InCarda. We recognized an impairment charge of $

2.9
million during the second quarter of 2023.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2023, we recorded $

4.8
million in fair value of InCarda's Series C preferred stock and $

0.1
million in fair value of Series D warrants. As of December 31, 2022, we recorded $

6.8
million in fair value of InCarda's Series C preferred stock and $

0.6
million in fair value of Series C warrants and Series D warrants. As of December 31, 2023 and 2022, we recognized $

2.7
million and $

3.2
million, respectively, for InCarda's Series D-1 preferred stock, Series D-2 preferred stock, and common stock using the measurement alternative. We recorded $

3.1
million, $

8.7
million, and $

0.7
million unrealized loss as changes in fair values of equity and long-term investments, net, in the consolidated statements of income for the years ended December 31, 2023, 2022, 2021, respectively.

Equity Investment in ImaginAb

On March 18, 2021, TRC entered into a securities purchase agreement with ImaginAb, Inc. ("ImaginAb") to purchase

4,051,724
shares of ImaginAb Series C preferred stock for $

4.7
million. On the same day, TRC also entered into a securities purchase agreement with one of ImaginAb's common stockholders to purchase

4,097,157
shares of ImaginAb common stock for $

1.3
million. ImaginAb is a privately held biotechnology company focused on clinically managing cancer and autoimmune diseases via molecular imaging. $

0.4
million was incurred for investment due diligence costs and execution and recorded as part of the equity investment in the consolidated balance sheets.

On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC's ownership interests and investments in ImaginAb.

On March 14, 2023, ITH entered into a securities purchase agreement with ImaginAb to purchase

270,568
shares of ImaginAb Series C-2 preferred stock for $

0.6
million. On September 14, 2023, ITH entered into a securities purchase agreement with ImaginAb to purchase another

405,852
shares of ImaginAb Series C-2 preferred stock for $

0.6
million. As of December 31, 2023,

one
of ImaginAb's six board members was designated by ITH. As of December 31, 2023 and 2022, we held

12.4
% and

12.7
%, respectively, of ImaginAb equity ownership.

Our investment in ImaginAb does not provide us with the ability to control or have significant influence over ImaginAb's operations. Based on our evaluation, we determined that ImaginAb is a VIE, but we are not the primary beneficiary of the VIE. We have not provided financial or other support that we were not previously contractually required to provide during the periods presented. Our maximum exposure to loss is equal to the amount we invested in the entity.

Because ImaginAb's equity securities are not publicly traded and do not have a readily determinable fair value, we account for our investment in ImaginAb's Series C preferred stock and common stock using the measurement alternative. As of December 31, 2023 and 2022, $

7.6
million and $

6.4
million, respectively, was recorded as equity and long-term investments in the consolidated balance sheets, respectively, and there was no change to the fair value of our investment in ImaginAb.

Convertible Promissory Note in Gate Neurosciences

On November 24, 2021, TRC entered into a Convertible Promissory Note Purchase Agreement with Gate to acquire a convertible promissory note (the "Gate Convertible Note") with a principal amount of $

15.0
million. Gate is a privately held biopharmaceutical company focused on developing the next generation of targeted nervous system therapies, leveraging precision medicine approaches to develop breakthrough drugs for psychiatric and neurologic diseases. The investment is intended to fund Gate's ongoing development and research. The Gate Convertible Note bears an annual interest rate of

8
% and will convert into shares of common stock of Gate upon a qualified event or into shares of shadow preferred stock of Gate ("Shadow Preferred") upon a qualified financing. A qualifying event can be a qualified initial price offering, a qualified merger, or a merger with a special-purpose acquisition company ("SPAC"). Shadow Preferred means preferred stock having identical rights, preferences and restrictions as the preferred stock that would be issued in a qualified financing.

The number of common stock shares to be issued in a qualified event shall be equal to the amount due on the conversion date divided by the lesser of a capped conversion price (the "Capped Conversion Price") and the qualified event price (the "Qualified Event Price"). The Capped Conversion Price is calculated as $50.0 million divided by the number of shares of common stock outstanding at such time on a fully diluted basis. The Qualified Event Price is the price per share determined by the qualified event. A qualified financing is a sale or series of sales of preferred stock where (i) at least 50 percent of counterparties are not existing shareholders, (ii) net proceeds to Gate are at least $35.0 million, and (iii) the stated or implied equity valuation of Gate is at least $80.0 million.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC's debt investments in Gate.

On February 2, 2023, ITH entered into a Note Amendment Agreement with Gate to amend the Gate Convertible Note. Pursuant to the Note Amendment Agreement, the principal amount of the Gate Convertible Note was increased from $

15.0
million to $

21.5
million, which represents the original principal, accrued interest as of the amendment date and an additional cash investment of $

5.0
million. All other material terms of the Gate Convertible Note were unchanged.

On October 6, 2023, ITH entered into a Second Note Amendment Agreement with Gate to amend the Note Amendment Agreement. Pursuant to the Second Note Amendment Agreement, the principal amount of the Gate Convertible Note was increased from $

21.5
million to $

27.7
million, which represents the amended principal as of February 2, 2023, accrued interest as of the second amendment date and an additional cash investment of $

5.0
million. All other material terms of the Gate Convertible Note were unchanged.

We have accounted for the Gate Convertible Note as a trading security, measured at fair value using a Monte Carlo simulation model with the probability of certain qualified events and the assumptions of equity value of Gate, risk-free rate, expected stock price, volatility of its peer companies, and the time until a financing is raised. As of December 31, 2023 and 2022, the fair value of the Gate Convertible Note was estimated at $

28.0
million and $

15.7
million, respectively, and recorded as equity and long-term investments in the consolidated balance sheets. We recorded $

0.4
million of unrealized loss, $

0.6
million of unrealized gain, and $

0.8
million of unrealized loss as changes in fair values of other equity and long-term investments, net, in the consolidated statements of income for the years ended December 31, 2023, 2022 and 2021, respectively.

Equity Investment in Nanolive

On February 18, 2022, TRC entered into an investment and shareholders agreement with Nanolive to purchase

18,750,000
shares of Nanolive Series C preferred stock for $

9.8
million (equivalent to

9.0
million CHF). Nanolive SA is a Swiss privately held life sciences company focused on developing breakthrough imaging solutions that accelerate research in growth industries such as drug discovery and cell therapy. $

0.7
million was incurred for investment due diligence costs and execution and recorded as part of the equity and long-term investment in the consolidated balance sheets. On July 20, 2022, under the terms of the TRC Equity Purchase Agreement, TRC transferred to ITH all of TRC's ownership interests and investments in Nanolive. ITH has the right to designate one member to Nanolive's board. ITH also has the right to designate another member, who will be mutually acceptable to ITH and another stockholder, to Nanolive's board. As of December 31, 2023,

no
Innoviva designee is serving on Nanolive's

six
-member board. As of December 31, 2023 and 2022, we held

15.3
% and

15.5
% of Nanolive equity ownership, respectively.

Our investment in Nanolive does not provide us with the ability to control or have significant influence over Nanolive's operations. Based on our evaluation, we determined that Nanolive is a VIE, but we are not the primary beneficiary of the VIE. We have not provided financial or other support that we were not previously contractually required to provide during the periods presented. Our maximum exposure to loss is equal to the amount we invested in the entity.

Because Nanolive's equity securities are not publicly traded and do not have a readily determinable fair value, we account for our investment in Nanolive's Series C preferred stock using the measurement alternative. As of December 31, 2023 and 2022, $

10.6

million of investment in Nanolive was recorded as equity and long-term investments in the consolidated balance sheets, and there was no change to the carrying amount of our investment.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	December 31, 2023			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds[1]	$ 170,706	$ —	$ —	$ 170,706
Total	$ 170,706	$ —	$ —	$ 170,706

[1] Money market funds are included in cash and cash equivalents in the consolidated balance sheets.

	December 31, 2022			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds[1]	$ 263,469	$ —	$ —	$ 263,469
Total	$ 263,469	$ —	$ —	$ 263,469

[1] Money market funds are included in cash and cash equivalents in the consolidated balance sheets.

As of December 31, 2023 and 2022, all available-for-sale securities were money market funds, and there was

no

credit loss recognized.

Fair Value Measurements

Our available-for-sale securities, equity and long-term investments and contingent value rights are measured at fair value on a recurring basis and our debt is carried at amortized cost basis.

	Estimated Fair Value Measurements as of December 31, 2023 Using:			
Types of Instruments (In thousands)	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Assets				
Money market funds	$ 170,706	$ —	$ —	$ 170,706
Investments held by ISP Fund LP [1]	251,207	—	60,605	311,812
Equity investment - Armata Common Stock	81,249	—	—	81,249
Equity investment - Armata Warrants	—	35,297	—	35,297
Convertible debt investment - Armata Note	—	—	51,883	51,883

Term loan investment - Armata Term Loan				
	—	—	27,044	27,044
Convertible debt investment - Gate Note				
	—	—	27,972	27,972
Total assets measured at estimated fair value				
	$ 503,162	$ 35,297	$ 167,504	$ 705,963
Liabilities				
Debt				
2025 Notes				
	$ —	$ 200,407	$ —	$ 200,407
2028 Notes				
	—	227,070	—	227,070
Total fair value of debt				
	$ —	$ 427,477	$ —	$ 427,477
Contingent value rights				
	—	—	359	359
Total liabilities at estimated fair value				
	$ —	$ 427,477	$ 359	$ 427,836

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(1) The investments held by ISP Fund LP, consisted of $ 248.5 million in equity investments, which included private placement positions of $ 60.6 million, and $ 62.9 million in money market funds. A certain portion of the total capital contribution of $ 300.0 million is no longer subject to a 36-month lock-up period from the date of such capital contribution. However, we did no t elect to make a withdrawal in 2023, thereby extending the lock-up period and withdrawal elections into subsequent years.

	Estimated Fair Value Measurements as of December 31, 2022 Using:			
Types of Instruments (In thousands)	**Quoted Price in Active Markets for Identical Assets Level 1**	**Significant Other Observable Inputs Level 2**	**Significant Unobservable Inputs Level 3**	**Total**
Assets				
Money market funds	$ 263,469	$ —	$ —	$ 263,469
Investments held by ISP Fund LP (1)	265,982	—	54,578	320,560
Equity investment - Armata Common Stock	31,095	—	—	31,095
Equity investment - Armata Warrants	—	8,059	—	8,059
Equity investment - InCarda Warrants	—	—	605	605
Convertible debt investment - Gate Note	—	—	15,700	15,700
Total assets measured at estimated fair value	$ 560,546	$ 8,059	$ 70,883	$ 639,488
Debt				
2023 Notes	$ —	$ 96,089	$ —	$ 96,089
2025 Notes	—	197,807	—	197,807
2028 Notes	—	211,768	—	211,768
Total fair value of debt	$ —	$ 505,664	$ —	$ 505,664
Contingent value rights	—	—	595	595

Total liabilities at estimated fair value	$ —	$ 505,664	$ 595	$ 506,259

(1) The investments held by ISP Fund LP, consisted of $

295.4
million in equity investments, which included private placement positions and convertible notes of $

54.6
million, and $

25.1
million in money market funds. Our total capital contribution of $

300.0
million was subject to a 36-month lock-up period from the date of such capital contributions.

The fair values of our equity investments in Armata's common stock and publicly traded 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 in the warrants in Armata 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 InCarda Warrants, the Gate Convertible Note, the Armata Convertible Note, the Armata Term Loan, private placement positions and convertible notes held by ISP Fund LP, and contingent value rights are classified as Level 3 financial instruments as these securities are not publicly traded and the assumptions used in the valuation model for valuing these securities are based on significant unobservable and observable inputs including those of publicly traded peer companies.

The fair values of our 2025 Notes and 2028 Notes are based on recent trading prices of the respective instruments. The fair values of our 2023 Notes, which were fully paid off in January 2023, were also based on their trading prices.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. CAPITALIZED FEES PAID

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

(In thousands)	Amortization period	December 31, 2023	2022
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		(136,216)	(122,393)
Net carrying value		$ 83,784	$ 97,607

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 recorded as a reduction in revenue from collaborative arrangements. As of December 31, 2023, the weighted average remaining amortization period was 6.2 years.

Additional information regarding these milestone fees is included in Note 3, “Revenue Recognition”. Amortization for each of the years ended December 31, 2023, 2022 and 2021 was $

13.8

million. The remaining estimated amortization is $

13.8

million for each of the years from 2024 to 2027, $

13.7
million for the year 2028, and $

14.8
million thereafter.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets acquired are recognized at fair value as of the acquisition date. The carrying amount of goodwill as of December 31, 2023 and 2022 was $

17.9
million and $

26.7
million, respectively. We have

no
t recognized any impairment losses related to goodwill and intangible assets during the periods presented.

Intangible assets with definite lives are amortized over their estimated useful lives. The carrying basis and accumulated amortization of recognized intangible assets as of December 31, 2023 and 2022 were as follows:

(In thousands)	Useful Life (Years)	December 31, 2023 Gross Amount	Accumulated Amortization	Net Carrying Amount
Marketed products	8 - 10	$ 219,700	$ (25,204)	$ 194,496
In-process research and development		2,600	—	2,600
Collaboration agreement	10	35,400	(2,161)	33,239
Total		$ 257,700	$ (27,365)	$ 230,335

(In thousands)	Useful Life (Years)	December 31, 2022 Gross Amount	Accumulated Amortization	Net Carrying Amount
Marketed products	8 - 10	$ 151,000	$ (5,581)	$ 145,419
In-process research and development		72,100	—	72,100
Collaboration agreement		35,400	—	35,400
Total		$ 258,500	$ (5,581)	$ 252,919

Intangible assets recognized as a result of the acquisition of Entasis amounted to $

106.7
million, which consisted of Entasis' in-process research and development related to its antibacterial therapeutic product candidates and a collaboration agreement amounting to $

71.3
million and $

35.4
million, respectively. Following the FDA approval of XACDURO® in May 2023, we started amortizing $

68.7
million of the then in-process research and development as a marketed product, as well as the collaboration agreement, over their estimated useful lives. The useful life of the remaining in-process research and development of $

2.6
million will be determined upon commercialization of the underlying product candidate; thus,

no
amortization expense for this intangible asset was recognized for the periods presented.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Intangible assets recognized as a result of the acquisition of La Jolla amounting to $

151.0

million pertain to product rights and developed technologies on La Jolla's currently marketed products. These are intangible assets with determinable lives and are amortized over their estimated useful lives.

We recognized amortization expense of $

21.8

million and $

5.6

million for the years ended December 31, 2023 and 2022, respectively. Future amortization expense is expected to be $

25.8

million for each of the years from 2024 to 2028 and $

98.7

million thereafter.

9. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following:

(In thousands)	December 31, 2023	2022
Raw materials	$ 11,257	$ 5,757
Work-in-process	15,670	25,052
Finished goods	13,810	25,088
Total inventory	$ 40,737	$ 55,897

As of December 31, 2023 and 2022, total inventory included net fair value adjustments resulting from the acquisition of La Jolla of approximately $

23.0

million and $

49.5

million, respectively, which will be recognized as cost of products sold when sales occur in future periods. The fair value adjustments recorded as part of cost of products sold amounted to $

27.2

million and $

10.0

million for the years ended December 31, 2023 and 2022.

Other Accrued Liabilities

Other accrued liabilities consisted of the following:

(In thousands)	December 31, 2023	2022

Accrued contract manufacturing expenses	$ 1,966	$ 8,382
Accrued clinical expenses	591	692
Accrued research expenses	185	349
Accrued professional services	8,876	3,977
Current portion of lease liabilities	1,207	1,316
Royalty obligation payable	1,928	—
Current portion of deferred royalty obligation	—	2,639
Accrued license fees and royalties	1,575	943
Other	3,370	2,909
Total other accrued liabilities	$ 19,698	$ 21,207

Other Long-Term Liabilities

Other long-term liabilities consisted of the following:

(In thousands)	December 31, 2023	2022
Long-term portion of deferred royalty obligation	$ 69,876	$ 67,947
Long-term portion of lease liabilities	1,635	$ 2,376
Contingent value rights liability	359	595
Total other long-term liabilities	$ 71,870	$ 70,918

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. 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, 2023, total shares remaining available for issuance under the 2012 Plan were

2,924,185
.

Employee Stock Purchase Plan

Under the 2004 Employee Stock Purchase Plan (the "2004 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 2004 ESPP provided 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 ended on either May 15 or November 15. The 2004 ESPP contributions were 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 was

2,500
. An employee may not purchase shares with a value greater than $

25,000
in any calendar year.

On April 13, 2023, the Board of Directors adopted the 2023 ESPP (the "2023 ESPP"). The 2023 ESPP, which supersedes the 2004 ESPP, was approved by the Company's stockholders on May 22, 2023. Under the 2023 ESPP, eligible 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 or end of each applicable purchase period. The 2023 ESPP provides for offering periods of six months , which ends on either May 15 or November 15. The 2023 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. A total of

2.5
million shares of our common stock was reserved and available for issuance under the 2023 ESPP.

As of December 31, 2023, total shares remaining available for issuance under the 2023 ESPP were

2,500,000
.

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. In October 2017, both the cash and equity components of the compensation program were amended, effective immediately (the "October 2017 Amendments").

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.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Selling, general and administrative	$ 4,645	$ 5,305	$ 2,017
Research and development	1,192	2,042	—
Total	$ 5,837	$ 7,347	$ 2,017

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

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Stock options	$ 1,980	$ 3,057	$ 490
RSUs	3,663	4,053	1,280
RSAs	168	194	200
ESPP	26	43	47
Total stock-based compensation expense	$ 5,837	$ 7,347	$ 2,017

As of December 31, 2023, 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	$ 4,861	2.9
RSUs	4,430	2.4
RSAs	220	1.9
Total unrecognized compensation expense	$ 9,511	

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, 2022	948	$ 15.56	518	$ 12.16	30	$ 14.97
Granted	828	$ 12.77	389	$ 12.85	—	$ —
Exercised	(2)	$ 12.98	—	$ —	—	$ —
Released RSUs and RSAs	—	$ —	(284)	$ 12.42	(14)	$ 15.02
Forfeited	(275)	$ 15.22	(141)	$ 11.98	—	$ —
Balance as of December 31, 2023	1,499	$ 14.09	482	$ 12.62	16	$ 14.93
Vested and expected to vest as of December 31, 2023	1,499	$ 14.09	482	$ 12.62	—	$ —

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2023, the aggregate intrinsic value of options outstanding and options exercisable was $

3.6
million and $

0.8
million, respectively. As of December 31, 2022, the aggregate intrinsic value of options outstanding and options exercisable was not material. As of December 31, 2023,

519,165
options were exercisable. The weighted average remaining contractual term of options outstanding was 7.96 years and 8.01 years as of December 31, 2023 and 2022, respectively.

The total intrinsic value of the options exercised was

no

t material for the year ended December 31, 2023, 2022 and 2021. The total estimated fair value of options vested was $

1.9
million and $

0.6
million for the years ended December 31, 2023 and 2021, respectively. The total estimated fair value of options vested was

no
t material for the year ended December 31, 2022.

The total estimated fair value of RSUs vested was $

3.9
million, $

2.3
million and $

1.1
million for the years December 31, 2023, 2022 and 2021.

The total estimated fair value of RSAs vested was not material for the year ended December 31, 2023, 2022, and 2021.

Valuation Assumptions

Black-Scholes-Merton assumptions used in calculating the estimated value of stock options granted by Innoviva on the date of grant were as follows:

	Year Ended December 31,		
	2023	2022	2021
Risk-free interest rate	4.0 %	3.6 %	1.1 %
Expected term (in years)	6.09	6.04	6.11
Volatility	37.8 %	38.6 %	44.9 %
Dividend yield	0.0 %	0.0 %	0.0 %
Weighted-average estimated fair value of stock options granted	$ 5.57	$ 6.43	$ 5.84

11. STOCKHOLDERS' EQUITY

On October 31, 2022, our board of directors authorized a share repurchase program under which we may repurchase up to $

100.0

million of our outstanding shares of common stock. The repurchase program authorizes the repurchase by the Company of its common stock in open market transactions, including pursuant to a trading plan in accordance with Rule 10b-18 promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) privately negotiated transactions, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination thereof or by other means in accordance with federal securities laws. The authorization permits the Company to repurchase shares of its common stock from time to time at management’s discretion. Repurchases may also be made pursuant to a trading plan under Rule 10b5-1 under the Exchange Act, which would permit shares to be repurchased when the Company might otherwise be precluded from doing so because of self-imposed trading blackout periods or other regulatory restrictions. The actual means and timing of any shares purchased under the program will depend on a variety of factors, including ongoing assessments of the capital needs of the business, the market price of our common stock, prevailing stock prices, general market conditions and other considerations. This program has no termination date, may be suspended or discontinued at any time at our discretion, and does not obligate us to acquire any amount of common stock. From program inception through December 31, 2022, we repurchased

647,394
shares in the open market at an average price of $

13.13
per share for a total amount of approximately $

8.5
million. For the year ended December 31, 2023, we repurchased

6,173,565
shares in the open market at an average price of $

12.39
per share for a total amount of approximately $

76.5
million. Subsequent to December 31, 2023 and through February 15, 2024, we have repurchased

131,826
shares in the open market at an average price of $

15.93
per share for a total amount of approximately $

2.1
million. All of the repurchased shares were retired.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DEBT

Our debt consists of the following:

(In thousands)	December 31, 2023	2022
2023 Notes	$ —	$ 96,204
2025 Notes	192,500	192,500
2028 Notes	261,000	261,000
Total debt	453,500	549,704
Less: Unamortized debt discount and issuance costs	(7,266)	(9,331)
Total debt, net	446,234	540,373
Less: Current portion of long-term debt, net	—	96,193
Total long-term debt, net	$ 446,234	$ 444,180

Convertible Subordinated Notes Due 2023

In January 2013, we completed an underwritten public offering of $ 287.5 million aggregate principal amount of our 2023 Notes, which matured on January 15, 2023. The 2023 Notes bore 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 represented 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 was 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 were subject to adjustments consistent with the 2023 Notes. The cap component was 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 coincided 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 was above $38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeded $38.00 per share, there was no incremental anti-dilutive benefit from the capped call.

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 represented 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 ended 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 March 7, 2022, we used $

165.6
million from the sale of the 2028 Notes to repurchase

60
% of the 2023 Notes with a face value of $

144.8
million. The carrying value of the repurchased 2023 Notes was $

144.5
million. Accrued interest was $

0.4
million and unamortized debt issuance costs were $

0.3
million on the date of repurchase. We recognized a loss on the extinguishment of the 2023 Notes of $

20.7
million in other expense, net, in the consolidated statement of operations. The repurchase reduced the outstanding principal balance to $

96.2
million and unamortized debt issuance costs to $

0.2
million. The annual effective interest rate of the 2023 Notes changed from

2.36
% to

2.37
%.

On April 18, 2022, certain 2023 Notes holders converted their notes of $

3.0
thousand into Innoviva’s common stock. The outstanding principal balance was reduced slightly to $

96.2
million.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Our outstanding 2023 Notes balance consisted of the following as of December 31, 2022:

(In thousands)	December 31, 2022
Principal	$ 96,204
Debt issuance costs, net	(11)
Net carrying amount	$ 96,193

The remaining balance of the 2023 Notes in the amount of $ 96.2 million was fully paid upon the maturity date in January 2023.

The following table sets forth total interest expense recognized related to the 2023 Notes for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
(In thousands)	2023	2022	2021
Contractual interest expense	$ 85	$ 2,617	$ 5,121
Amortization of debt issuance costs	11	302	580
Total interest and amortization expense	$ 96	$ 2,919	$ 5,701

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, as described below. 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.

Holders of the 2025 Notes may convert all or a portion of their 2025 Notes prior to the close of business on February 15, 2025 only under the following circumstances:

• after September 30, 2017, if our closing common stock price for at least 20 days out of the most recent 30 consecutive trading days of the preceding quarter is greater than

130
% of the current conversion price of the 2025 Notes;

• for five consecutive business days, if the average trading price per $1,000 of Notes during the prior 10 consecutive trading days is less than

98
% of the product of our closing common stock price and the conversion rate of the 2025 Notes on such day; and,

• upon the occurrence of specified corporate events, including certain distributions, the occurrence of a fundamental changes (as defined in the indenture governing the 2025 Notes) or a transaction resulting in our common stock converting into other securities or property or assets.

On or after February 15, 2025, holders of the 2025 Notes may convert their 2025 Notes at any time until the close of business on the second scheduled trading day immediately preceding the maturity date of the 2025 Notes.

In the event of default or a fundamental change (as defined above), holders of the 2025 Notes may require us to repurchase all or a portion of their 2025 Notes at price equal to

100
% of the principal amount of the 2025 Notes, plus any accrued and unpaid interest.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Effective January 1, 2022, we adopted ASU 2020-06 using a modified retrospective method, under which financial results reported in prior periods were not adjusted.

Prior to the adoption of ASU 2020-06, we separately accounted 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") was amortized to interest expense using the effective interest method over the term of the 2025 Notes. The equity component was not remeasured as long as it continued to meet the conditions for equity classification. Additionally, we separated the total issuance costs of $ 5.4 million incurred into liability and equity components in proportion to the allocation of the initial proceeds, resulting in liability issuance costs of $ 3.5 million and equity issuance costs of $ 1.9 million. Issuance costs attributable to the liability component were amortized on a straight-line basis, which approximated the effective interest rate method, to interest expense over the term of the 2025 Notes. The issuance costs attributable to the equity component were netted against the equity component in additional paid-in capital. The annual effective interest rate of the liability component of the 2025 Notes was 8.87%.

Upon adoption of ASU 2020-06 on January 1, 2022, we combined the liability and equity components of the 2025 Notes assuming that the instrument was accounted for as a single liability from inception to the date of adoption. We similarly combined the liability and equity components of the issuance costs. The issuance costs are presented as a deduction from the outstanding principal balance of the 2025 Notes and are amortized on a straight-line basis over the term of the 2025 Notes under the effective interest rate method. As of January 1, 2022, the annual effective interest rate on the 2025 Notes was 2.88%. Beginning January 1, 2022, the annual effective interest rate on the 2025 Notes is 2.88%.

Our outstanding 2025 Notes balances consisted of the following:

	December 31,	
(In thousands)	**2023**	**2022**
Principal	$ 192,500	$ 192,500
Debt discount and issuance costs, net	(1,205)	(1,917)
Net carrying amount	$ 191,295	$ 190,583

The following table sets forth total interest expense recognized related to the 2025 Notes for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Contractual interest expense	$ 4,813	$ 4,813	$ 4,813
Amortization of debt issuance costs	712	692	657
Amortization of debt discount	—	—	7,898

Total interest and amortization expense			
	5,525	5,505	13,368
	$	$	$

Convertible Senior Notes Due 2028

In March 2022, we completed a private placement of $ 261.0 million aggregate principal amount of our 2028 Notes, which will mature on March 15, 2028 . The proceeds include the 2028 Notes sold pursuant to the $ 45.0 million over-allotment option granted by us to the initial purchasers, of which $ 36.0 million was exercised. The 2028 Notes were sold in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The net proceeds from the sale of the $

261.0

million aggregate principal amount of 2028 Notes were approximately $

252.6

million after deducting the initial purchasers' discounts and commissions and our estimated offering expenses. We used approximately $

21.0

million of the net proceeds from the offering to fund the cost of entering into the capped call transactions described below. In addition, we used $

165.6

million of the remaining net proceeds to repurchase $

144.8

million aggregate principal amount of the 2023 Notes in separate and individually negotiated transactions with certain holders of the 2023 Notes, which closed concurrently with the issuance of the 2028 Notes. We expect to use the remaining net proceeds for general corporate purposes.

The 2028 Notes bear interest at an annual rate of

2.125

% that is payable semi-annually in arrears in cash on March 15 and September 15 of each year, beginning on September 15, 2022.

The 2028 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 was

38.1432

shares per $1,000 principal amount of the 2028 Notes, subject to customary anti-dilution adjustment in certain circumstances, which represented an initial conversion price of approximately $

26.22

per share.

Prior to September 15, 2027, the 2028 Notes will be convertible at the option of the holders only upon the occurrence of specified events and during certain periods, and will be convertible on or after September 15, 2027, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date of the 2028 Notes.

Holders of the 2028 Notes may convert all or a portion of their 2028 Notes prior to the close of business on September 15, 2027, only under the following circumstances:

- after March 31, 2022, if our closing common stock price for at least 20 days out of the most recent 30 consecutive trading days of the preceding quarter is greater than

  130

  % of the current conversion price of the 2028 Notes;
- for five consecutive business days, if the average trading price per $1,000 of Notes during the prior 10 consecutive trading days is less than

  98

  % of the product of our closing common stock price and the conversion rate of the 2028 Notes on such day; and,
- upon the occurrence of specified corporate events, including certain distributions, the occurrence of a fundamental changes (as defined in the indenture governing the 2028 Notes) or a transaction resulting in our common stock converting into other securities or property or assets.

On or after September 15, 2027, holders of the 2028 Notes may convert their 2028 Notes at any time until the close of the business on the second day immediately preceding the maturity date of the 2028 Notes.

The 2028 Notes will be redeemable, in whole or in part, at our option at any time, and from time to time, on or after March 20, 2025, and on or before the 75th scheduled trading day immediately before the maturity date but only if the last reported sale price per share of our common stock exceeds 130% of the conversion price for a specified period of time. The redemption price will be equal to the principal amount of the 2028 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, calling any 2028 Note for redemption will constitute a make-whole fundamental change (as defined in the indenture governing the 2028 Notes) with respect to that 2028 Note, in which case the conversion rate applicable to the conversion of that 2028 Note will be increased in certain circumstances if it is converted after it is called for redemption.

If we undergo a fundamental change, subject to certain conditions, holders may require us to purchase for cash all or any portion of their 2028 Notes. The fundamental change purchase price will be

100

% of the principal amount of the 2028 Notes to be purchased plus any accrued and unpaid interest to, but excluding, the fundamental change purchase date.

The indenture governing the 2028 Notes contains customary terms and covenants, including a merger covenant and that upon certain events of default occurring and continuing, either the Trustee or the holders of at least 25% of the aggregate principal amount of the outstanding Notes may declare 100% of the principal of, and accrued and unpaid interest, if any, on, all the Notes to be due and payable immediately.

In connection with the offering of the 2028 Notes, we entered into privately negotiated capped call transactions. The cap price of the capped call transaction is initially $

33.9850

per share and is subject to certain adjustments under the terms of the capped call transactions. The capped call transactions cover, subject to

customary adjustments, the number of shares of common stock initially

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

underlying the 2028 Notes. The capped call transactions are expected generally to reduce potential dilution to our common stock upon conversion of the 2028 Notes or at our election (subject to certain conditions) offset any cash payments we are required to make in excess of the aggregate principal amount of converted 2028 Notes, as the case may be, with such reduction or offset subject to a cap.

The annual effective interest rate on the 2028 Notes is 2.70%.

Our outstanding 2028 Notes balance consisted of the following:

(In thousands)	December 31, 2023	2022
Principal	$ 261,000	$ 261,000
Debt discount and issuance costs, net	(6,061)	(7,403)
Net carrying amount	$ 254,939	$ 253,597

The following table sets forth total interest expense recognized related to the 2028 Notes for the year ended December 31, 2023 and from the issuance through December 31, 2022:

(In thousands)	Year Ended December 31, 2023	Date of Issuance through December 31, 2022
Contractual interest expense	$ 5,546	$ 4,514
Amortization of debt discount and issuance costs	1,342	1,061
Total interest and amortization expense	$ 6,888	$ 5,575

Debt Maturities

The aggregate scheduled maturities of our convertible debt as of December 31, 2023 are as follows:

(In thousands)	Amount
Year ending December 31,	
2024	$ —
2025	192,500
2026	—
2027	—
2028	261,000
Total	$ 453,500

Deferred Royalty Obligation

As part of our acquisition of La Jolla, we recorded the fair value of its deferred royalty obligation in connection with La Jolla's royalty financing agreement ("La Jolla Royalty Agreement") with HealthCare Royalty Partners ("HCR"). Under the terms of the La Jolla Royalty Agreement, HCR is entitled to receive quarterly royalties on worldwide net sales of GIAPREZA® until either January 1, 2031 or when the maximum aggregate royalty payments have been made, whichever occurs first. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. The current maximum royalty rate is

14
%. Starting January 1, 2024, the maximum royalty rate was increased to

18
% based on the terms of the Agreement. The La Jolla Royalty Agreement is subject to maximum aggregate royalty payments to HCR of $

225.0
million.

For the years ended December 31, 2023, we recognized interest expense of $

6.5
million on the deferred royalty obligation. From the date of our acquisition of La Jolla through December 31, 2022, we recognized interest expense of $

1.8
million on the deferred royalty obligation. The carrying value of the deferred royalty obligation as of December 31, 2023 and 2022 was $

69.9
million and $

70.6
million, respectively, (refer to Note 9 "Balance Sheet Components"). During the year ended December 31, 2023, we made royalty payments to HCR of $

5.4
million. From the date of acquisition of La Jolla through December 31, 2022, we made royalty payments to HCR of $

1.0
million. The deferred royalty obligation was valued using Level 3 inputs, and its carrying value as of December 31, 2023 and 2022 approximates fair value. The fair value of the deferred royalty obligation was calculated as the

discounted deferred royalty obligations based on revenue projections for GIAPREZA®. As of December 31, 2023, the annual effective interest rate of the deferred royalty obligation is

16.46
%.

Under the terms of the La Jolla Royalty Agreement, if we are unable to meet certain obligations, including the obligation to use commercially reasonable and diligent efforts to commercialize GIAPREZA®, HCR would have the right to terminate the La Jolla Royalty Agreement and demand payment of either $

125.0
million or $

225.0
million (depending on which obligation we have failed to meet) less aggregate royalties already paid to HCR. As of December 31, 2023, inclusive of the aggregate royalties paid to HCR by La Jolla under the La Jolla Royalty Agreement prior to our acquisition, La Jolla paid $

18.1
million of aggregate royalties to HCR. In the event that we fail to pay such amount if and when due in a timely manner, HCR would have the right to foreclose on the GIAPREZA®-related assets. HCR has no recourse against any asset other than GIAPREZA®.

Certain contract provisions within the La Jolla Royalty Agreement that could result in an acceleration of amounts due under the La Jolla Royalty Agreement are recognized as embedded derivatives that require bifurcation from the deferred royalty obligation and fair value recognition. We determined the fair value of each derivative by assessing the probability of each event occurring, as well as the potential repayment amounts and timing of such repayments that would result under various scenarios. As a result of this assessment, we determined that the fair value of the embedded derivatives is immaterial and, therefore, not recognized as of December 31, 2023 and 2022. We estimate the fair value of the embedded derivatives for each reporting period until either the features lapse or the La Jolla Royalty Agreement is terminated, whichever occurs first. Any material change in the fair value of the embedded derivatives will be recorded as either a gain or loss in the consolidated statements of income.

13. COMMITMENTS AND CONTINGENCIES

Operating Lease

We have operating leases for our corporate headquarters, office spaces and laboratory facilities.

Our operating leases include a facility lease consisting of

20,062
square feet of office and laboratory space in Waltham, Massachusetts. Effective April 2022, we exercised our renewal option for to extend the lease term for three additional years through December 2025.

In 2019, we entered into an operating lease for our headquarters in Burlingame, California for approximately

2,111
rentable square feet. The lease commenced in November 2019 with an initial term of thirty-six calendar months, which was subsequently amended to expire in December 2027.

The components of lease costs are as follows:

	Year Ended December 31,	
(In thousands)	**2023**	**2022**
Straight line operating lease costs	$ 1,428	$ 1,585
Variable lease costs	189	155
Total lease costs	$ 1,617	$ 1,740

Supplemental cash flow information related to leases are as follows:

	Year Ended December 31,	
(In thousands)	**2023**	**2022**
Cash paid for amounts included in the measurement of operating lease liabilities:	$ 1,542	$ 790
Operating lease right-of-use assets obtained in exchange for operating lease obligations	—	3,323

Right-of-use assets obtained through acquisitions		
	—	1,185

As of December 31, 2023, our operating leases have weighted-average remaining term of approximately 2.3 years and the weighted-average discount rate on our operating lease liabilities was 7.6 %.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

We have not presented the comparative information above for the year ended December 31, 2021 as our operating lease during this year was not material.

Future minimum lease payments on our operating leases as of December 31, 2023 are as follows:

(In thousands)	Amount
Year ending December 31,	
2024	$ 1,373
2025	1,428
2026	143
Thereafter	149
Total undiscounted lease payments	3,093
Less: imputed interest	(251)
Total operating lease liabilities	$ 2,842

Legal Proceedings

From time to time, the Company is involved in legal proceedings in the ordinary course of its business. We are not currently a party to any material legal proceedings except as discussed below.

On February 15, 2022, La Jolla received a paragraph IV notice of certification (the "First Notice Letter") from Gland Pharma Limited ("Gland") advising that Gland had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to manufacture, use or sell a generic version of GIAPREZA® in the U.S. prior to the expiration of U.S. Patent Nos.: 9,220,745; 9,572,856; 9,867,863; 10,028,995; 10,335,451; 10,493,124; 10,500,247; 10,548,943; 11,096,983; and 11,219,662 (the "GIAPREZA® Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The First Notice Letter alleges that the GIAPREZA® Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the generic product described in Gland's ANDA.

On March 29, 2022, La Jolla filed a complaint for patent infringement of the GIAPREZA® Patents against Gland and certain related entities in the United States District Court for the District of New Jersey in response to Gland's ANDA filing. In accordance with the Hatch-Waxman Act, because GIAPREZA® is a new chemical entity and La Jolla filed a complaint for patent infringement within 45 days of receipt of the First Notice Letter, the FDA cannot approve Gland's ANDA any earlier than 7.5 years from the approval of the GIAPREZA® NDA unless the District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable and/or not infringed.

On February 22, 2023, La Jolla received a paragraph IV notice of certification (the "Second Notice Letter") from Gland advising that Gland had amended its ANDA filing to include a paragraph IV certification alleging that all claims of the newly-issued and Orange Book-listed U.S. Patent No. 11,559,559 ("the '559 Patent"), which covers GIAPREZA®, are invalid, unenforceable and/or not infringed.

On March 22, 2023, La Jolla filed a First Amended Complaint in this litigation adding Gland's marketing and distribution partners for its ANDA angiotensin II product, Fresenius Kabi USA LLC and Fresenius Kabi SwissBiosim GmbH (collectively, the "Fresenius Kabi Defendants"), as co-defendants. On April 7, 2023, La Jolla filed a Second Amended Complaint in response to the Second Notice Letter, adding claims that the manufacture, use, sale, offer for sale, or import of Gland's ANDA angiotensin II product will infringe the '559 Patent. On November 14, 2023, La Jolla filed a Third Amended Complaint adding additional infringement claims against the Fresenius Kabi Defendants. We intend to vigorously enforce our intellectual property rights relating to GIAPREZA®.

Fact discovery is set to conclude on February 29, 2024 and expert discovery will be complete by July 12, 2024. A trial date has not yet been set in this matter.

Given the early stage of this matter, we cannot reasonably estimate a potential future loss or a range of potential future losses, if any, and have not recorded a contingent liability accrual as of December 31, 2023.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Indemnifications and Other Contingencies

In the ordinary course of business, we may provide indemnifications of varying scope and terms to vendors, directors, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by us, our negligence or willful misconduct, violations of law, or intellectual property infringement claims made by third parties. In addition, we have entered into indemnification agreements with directors and certain officers and employees that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers, or employees. No material demands have been made upon us to provide indemnification under such agreements, and thus, there are no claims that we are aware of that could have a material effect in our consolidated financial statements. We also maintain director and officer insurance, which may cover certain liabilities arising from our obligation to indemnify our directors. To date, we have not incurred any material costs and, as of December 31, 2023, we have not accrued any liabilities in the consolidated financial statements as a result of these provisions.

14. INCOME TAXES

Income tax expense consists of the following:

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Current			
Federal	$ 7,799	$ 40,822	$ —
State	2,177	464	7
Total current	9,976	41,286	7
Deferred			
Federal	6,594	26,026	70,893
State	(2,194)	(625)	5,539
Total deferred	4,400	25,401	76,432
Total income tax expense, net	$ 14,376	$ 66,687	$ 76,439

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

	Year Ended December 31,		
(In thousands)	**2023**	**2022**	**2021**
Expected tax at federal statutory rate	$ 40,747	$ 58,928	$ 93,507
State income tax, net of federal benefit	1,433	(1,414)	848
Federal and state research credits	(1,582)	(2,453)	1,260
Section 250 deduction	(15,274)	—	—
Noncontrolling interest	—	7,468	(21,626)

Impact of consolidation and deconsolidation of subsidiaries	—	(8,897)	—
Other	1,219	(125)	1,129
Change in valuation allowance	(12,167)	13,180	1,321
Total income tax expense, net	$ 14,376	$ 66,687	$ 76,439

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	December 31,	
(In thousands)	**2023**	**2022**
Deferred tax assets		
Net operating loss carryforwards	$ 182,013	$ 149,646
Research and development tax credit carryforwards	21,357	21,230
Unrealized loss on investment, net	—	6,032
Deferred royalty obligation, net	18,084	17,404
Other	6,467	8,527
Total deferred tax assets before valuation allowance	227,921	202,839
Valuation allowance	(169,249)	(144,808)
Total deferred tax assets	58,672	58,031
Deferred tax liabilities		
Depreciation and amortization	(39,064)	(50,587)
Unrealized gain on investment, net	(13,747)	—
Inventory fair value adjustment	(6,424)	(12,410)
Other	—	(805)
Net deferred tax liabilities	$ (563)	$ (5,771)

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

As of December 31, 2023, we had federal net operating loss carryforwards of approximately $

543.5
million, which will expire beginning 2034. As of December 31, 2023, we also had state net operating loss carryforwards of approximately $

1.0
billion, which will expire beginning 2029 and state research tax credits of approximately $

33.3
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 of the Company through December 31, 2022 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. If we ever undergo an 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.

As a result of the acquisition of Entasis, we conducted a study of Entasis' ownership changes and estimated that we will be able to utilize $

155.6
million of its federal net operating losses, which are subject to annual limitations.

INNOVIVA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As a result of the acquisition of La Jolla, we also performed an analysis of its ownership changes and estimated that we will be able to utilize $ 309.5 million of its federal net operating losses, which are subject to annual limitations.

Our policy is to recognize interest and/or penalties related to income tax matters in income tax expense. As of December 31, 2023 and 2022, we had no accrued interest or penalties due to the Company's net operating losses available to offset any tax adjustments.

Uncertain Tax Positions

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

(In thousands)	Amount
Unrecognized tax benefits as of December 31, 2020	15,185
Net decrease in tax portions for 2021	(313)
Unrecognized tax benefits as of December 31, 2021	14,872
Net increase in tax portions for 2022	1,452
Unrecognized tax benefits as of December 31, 2022	16,324
Net increase in tax portions for 2023	3,119
Unrecognized tax benefits as of December 31, 2023	$ 19,443

We are subject to taxation in the U.S. and various state jurisdictions. The tax years 2006 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.

In December 2021, the Organization for Economic Cooperation and Development ("OECD") enacted model rules for a new global minimum tax framework ("BEPS Pillar Two"), and various governments around the world have enacted, or are in the process of enacting legislation. We are in the process of evaluating whether and when these new rules may come into effect and apply to us. We plan to treat the tax if any as a period cost. We do not believe that the Pillar Two rules apply to us yet. As such, the potential future quantitative impact of the enacted or substantively enacted legislation is not yet reasonably estimable.

15. SUBSEQUENT EVENTS

On February 13, 2024, ITH entered into a Third Note Amendment Agreement with Gate to amend the Gate Convertible Note. Pursuant to the Third Note Amendment Agreement, the principal amount of the Gate Convertible Note was increased from $ 27.7 million to $ 33.5 million, which represents the principal and accrued interest as of the amendment date and an additional cash investment of $ 5.0 million. All other material terms of the Gate Convertible Note were unchanged.

On February 23, 2024, ITH purchased a subordinated convertible promissory note (the "ImaginAb Convertible Note") from ImaginAb for a total purchase price of $ 2.7 million. The ImaginAb Convertible Note bears an annual interest of 10 % and shall be due and payable upon the earlier to occur of January 31, 2025 and certain events defined in the ImaginAb Convertible Note. Under

certain circumstances, the ImaginAb Convertible Note is convertible at the option of ITH into ImaginAb's equity securities at defined conversion prices. The ImaginAb Convertible Note is subordinate to certain existing indebtedness of ImaginAb as defined in the ImaginAb Convertible Note.

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 accompanying consolidated balance sheets of Innoviva, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 29, 2024, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 audits 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.

Consolidated Entities and Equity and Long-term Investments—Primary Beneficiary Determination for Variable Interest Entity—Refer to Notes 1, 5, and 6 to the consolidated financial statements.

Critical Audit Matter Description

The Company invests in equity and debt securities of private and public companies. The Company evaluates its interests in these entities to determine whether they meet the definition of a variable interest entity (VIE) or a voting interest entity (VOE) and whether the Company is required to consolidate these entities. A VIE is consolidated by its primary beneficiary, which is the party that has both 1) the power to direct the activities that most significantly impact the economic performance of the VIE and 2) a variable interest that could potentially be significant to the VIE. To determine whether a variable interest that the Company holds could potentially be significant to the VIE, the Company considers both qualitative and quantitative factors regarding the nature, size, and form of the Company's involvement with the VIE. The Company will reconsider whether an entity is a VIE and whether the Company is the primary beneficiary of the entity upon the occurrence of certain types of events. The determination of the primary beneficiary of a VIE requires significant management judgement.

We identified the primary beneficiary determination for the Company's VIEs as a critical audit matter due to the complexity of the accounting principles related to the determination of the primary beneficiary of a VIE and the significant judgment required by management in evaluating the agreements and structure of the investments in determining the primary beneficiary of a VIE. This required a high degree of auditor judgment and an increased extent of effort, including the involvement of professionals with consolidation accounting expertise, when performing audit procedures to evaluate the Company's determination of whether it is the primary beneficiary for its VIEs.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the primary beneficiary determination for VIEs included the following, among others:

- We tested the effectiveness of controls over the Company's primary beneficiary determination for its VIEs, including management's determination of the party that has the power to direct the activities that most significantly impact the economic performance of the VIE and a variable interest that could potentially be significant to the VIE.
- We evaluated the appropriateness of the Company's accounting conclusions for consolidated and unconsolidated VIEs through the following:
    - Evaluated the investment structures and terms of the agreements, including reading the purchase agreements and other related documents.
    - Tested whether the Company appropriately determined the primary beneficiary by evaluating the contractual arrangements of the entity to determine if the Company has the power to direct activities that most significantly impact the economic performance of the VIE 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.
    - For certain VIEs, with the assistance of professionals with expertise in consolidation accounting, evaluated the appropriateness of the Company's determination of the primary beneficiary of the VIE.
    - Evaluated the Company's disclosures related to the primary beneficiary determination of its consolidated entities and equity and long-term investments.

/s/ Deloitte & Touche LLP

San Jose, California
February 29, 2024

We have served as the Company's auditor since 2022.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the financial statements
We have audited the consolidated balance sheet of Innoviva, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2021 (not presented herein), the related consolidated statements of income, comprehensive income, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("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 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 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 audit provides a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We served as the Company's auditor from 2019 to 2021.

San Francisco, California
February 29, 2024

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, 2023, 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 specified in the Commission's rules and forms and controls and procedures that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decision regarding required disclosure. 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, 2023.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited our internal control over financial reporting as of December 31, 2023. 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 errors and all frauds. 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

We completed our acquisitions of Entasis and La Jolla in 2022. We integrated the acquired operations and processes into our internal control environment and implemented necessary changes to our internal control over financial reporting, including, but not limited, to the creation of new controls related to inventory management, research and development activities and product sales.

Other than the above, there have been more material changes to our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) for the year ended December 31, 2023 which have materially affected, or are 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. and subsidiaries (the "Company") as of December 31, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* 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, 2023, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2023, of the Company and our report dated February 29, 2024, 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/ Deloitte & Touche LLP

San Jose, California
February 29, 2024

ITEM 9B. OTHER INFORMATION

Trading Arrangements

None of the Company's directors or officers adopted , modified , or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the Company's fiscal quarter ended December 31, 2023.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

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 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

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, 2023:

Plan Category	Number of securities to be issued upon exercise of outstanding options and vesting of outstanding restricted stock units and restricted stock awards (a)		Weighted-average exercise price of outstanding options (b)		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	1,981,403	(1)	14.09	(2)	5,424,185	(3)

(1) Includes 1,499,312 shares issuable upon exercise of outstanding options and 482,091 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 2,500,00 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 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2023.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements:

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

2. Financial Statement Schedules:

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

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

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

ITEM 16. FORM 10-K SUMMARY

None.

Exhibits

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing Date/Period End Date	
2.1	Agreement and Plan of Merger, dated as of May 23, 2022, by and among Innoviva, Inc., Innoviva Merger Sub, Inc. and Entasis Therapeutics	8-K	2.1	5/24/2022	
2.2	Agreement and Plan of Merger, dated as of July 10, 2022, by and among Innoviva, Inc., Innoviva Acquisition Sub, Inc. and La Jolla Pharmaceutical Company	8-K	2.1	7/11/2022	
3.1	Amended and Restated Certificate of Incorporation	8-K	99.2	4/28/2016	
3.2	Amended and Restated Bylaws, amended and restated as of January 1, 2023	8-K	3.1	1/4/2023	
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)	8-K	4.2	1/25/2013	
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	
4.6	Indenture (including form of Note) with respect to Innoviva's 2.125% Convertible Senior Notes due 2028, dated as of March 7, 2022, between Innoviva, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	4.1	3/8/2022	
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	
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+	Offer Letter between Innoviva, Inc. and Pavel Raifeld, dated April 29, 2022	8-K	10.1	5/2/2022	
10.27	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	
10.28	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	
10.29	Share Repurchase Agreement, dated as of May 2021, by and between Innoviva, Inc. and Glaxo Group Limited	8-K	10.1	5/20/2021	
10.30	Letter Agreement, dated as of May 20, 2021, by and among Innoviva Strategic Partners LLC, ISP Fund LP and Sarissa Capital Fung GP LP	8-K	10.2	5/20/2021	
10.31	Capped Call Confirmation dated March 2, 2022, by and among Innoviva, Inc., Bank of America, N.A., Goldman Sachs & Co. LLC and Deutsche Bank AG, London Branch	8-K	10.1	3/8/2022	
10.32	Amendment No. 1 to the Investor Rights Agreement, dated May 23, 2022, by and among Innoviva, Inc. and Entasis Therapeutics Holdings Inc.	8-K	10.1	5/24/2022	
10.33	Support Agreement, dated July 10, 2022, by and among Innoviva, Inc., Innoviva Acquisition Sub, Inc., Tang Capital Partners, LP and Kevin C. Tang Foundation	8-K	10.1	7/11/2022	
10.34	Equity Purchase Agreement, dated July 13, 2022, by and among Innoviva, Inc., Innoviva TRC Holdings LLC and Royalty Pharma Investments 2019 ICAV	8-K	10.1	7/13/2022	
10.35	Third Amendment to Collaboration Agreement, dated July 13, 2022, by and among Innoviva, Inc., Glaxo Group Limited, and Theravance Respiratory Company, LLC.	8-K	10.2	7/13/2022	
10.36+	Transition Agreement between Larry Edwards and Innoviva Specialty Therapeutics, Inc., dated February 23, 2023, and Release of Claims form signed by Larry Edwards, dated April 5, 2023	10-Q	10.1	5/9/2023	
10.37	2023 Employee Stock Purchase Plan	DEF 14A		4/28/2023	
10.38+	Offer Letter between Innoviva, Inc. and Stephen Basso dated July 28, 2023	8-K	10.1	8/25/2023	
21.1	List of Subsidiaries				X
23.1	Consent of Independent Registered Public Accounting Firm				X
23.2	Consent of Independent Registered Public Accounting Firm				X
23.3	Consent of Ernst & Young LLP Independent Registered Public Accounting Firm of Armata Pharmaceuticals, Inc.**				
24.1	Power of Attorney (see signature page to this Annual Report on Form 10-K)				X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934				X

31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14 under the Securities Exchange Act of 1934	X
32#	Certifications Pursuant to 18 U.S.C. Section 1350	
97	Innoviva Clawback Policy (effective as of October 2, 2023)	X
99.1	Audited Consolidated Financial Statements of Armata Pharmaceuticals, Inc. at December 31, 2023, for the year ended December 31, 2023**	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

+ 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.
** To be filed by amendment to this Annual Report on Form 10-K.
# Furnished herewith.

SIGNATURES

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

INNOVIVA, INC.

Date: February 29, 2024

By: /s/ PAVEL RAIFELD
Pavel Raifeld
Chief Executive Officer

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.

Signature	Title	Date
/s/ PAVEL RAIFELD Pavel Raifeld	Chief Executive Officer (Principal Executive Officer)	February 29, 2024
/s/ STEPHEN BASSO Stephen Basso	Chief Financial Officer (Principal Financial Officer)	February 29, 2024
/s/ MARK DIPAOLO Mark DiPaolo, Esq.	Chairman of the Board	February 29, 2024
/s/ ODYSSEAS KOSTAS Odysseas Kostas, M.D.	Director	February 29, 2024
/s/ JULES HAIMOVITZ Jules Haimovitz.	Director	February 29, 2024
/s/ SARAH SCHLESINGER Sarah Schlesinger, M.D.	Director	February 29, 2024
/s/ SAPNA SRIVASTAVA Sapna Srivastava, Ph.D.	Director	February 29, 2024

Exhibit 21.1

LIST OF SUBSIDIARIES

Name	Jurisdiction	Ownership Interest
Advanced Medicine East, Inc	Delaware	100%
Innoviva Strategic Partners LLC	Delaware	100%
Innoviva Royalty Sub LLC	Delaware	100%
Innoviva TRC Holdings LLC	Delaware	100%
Innoviva Strategic Opportunities LLC	Delaware	100%
ISP Fund LLP	Delaware	100%
Innoviva Specialty Therapeutics Holdings LLC	Delaware	100%
Innoviva Specialty Therapeutics Inc.	Delaware	100%
Entasis Therapeutics Holdings Inc.	Delaware	100%
Entasis Therapeutics Inc.	Delaware	100%
Entasis Therapeutics Limited	United Kingdom	100%
Entasis Therapeutics Security Corporation	Massachusetts	100%
Entasis Therapeutics (Ireland) Limited	Ireland	100%
La Jolla Pharmaceutical Company	Delaware	100%
La Jolla Pharma, LLC	Delaware	100%
Tetraphase Pharmaceuticals, Inc.	Delaware	100%
La Jolla Pharmaceutical Holdings, LLC	Delaware	100%
La Jolla Pharmaceutical I B.V.	Netherlands	100%
La Jolla Pharmaceutical II B.V.	Netherlands	100%
La Jolla Pharmaceutical III B.V.	Netherlands	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-275502, 333-119559, 333-129669, 333-150753, 333-159042, 333-173923, 333-181763, and 333-197950 on Form S-8 of our reports dated February 29, 2024, relating to the financial statements of Innoviva, Inc. and the effectiveness of Innoviva, Inc.'s internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

San Jose, California
February 29, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated February 28, 2022, with respect to the consolidated financial statements included in the Annual Report of Innoviva, Inc. on Form 10-K for the year ended December 31, 2023. We consent to the incorporation by reference of said report 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, File No. 333-197950, and File No. 333-275502).

/s/ GRANT THORNTON LLP

San Francisco, California
February 29, 2024

Exhibit 31.1

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 29, 2024

/s/ PAVEL RAIFELD
Pavel Raifeld
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Stephen Basso, 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 29, 2024

/s/ STEPHEN BASSO
Stephen Basso
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL ACCOUNTING OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Pavel Raifeld, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Innoviva, Inc. on Form 10-K for the fiscal year ended December 31, 2023 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition of Innoviva, Inc. at the end of the periods covered by such Annual Report on Form 10-K and results of operations of Innoviva, Inc. for the periods covered by such Annual Report on Form 10-K.

Date: February 29, 2024 By: /s/ PAVEL RAIFELD
Pavel Raifeld
Chief Executive Officer
(Principal Executive Officer)

I, Stephen Basso, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Innoviva, Inc. on Form 10-K for the fiscal year ended December 31, 2023 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition of Innoviva, Inc. at the end of the periods covered by such Annual Report on Form 10-K and results of operations of Innoviva, Inc. for the periods covered by such Annual Report on Form 10-K.

Date: February 29, 2024 By: /s/ STEPHEN BASSO
Stephen Basso
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Innoviva, Inc. and will be retained by it and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 97

INNOVIVA, INC.
POLICY FOR THE
RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

1. **Purpose**. The purpose of this Policy is to describe the circumstances in which Executives will be required to repay or return Erroneously Awarded Compensation to members of the Company Group. Each Executive Officer shall be required to sign and return to the Company the Acknowledgement Form attached hereto as Exhibit A pursuant to which such Executive Officer will agree to be bound by the terms and comply with this Policy.

2. **Administration**. This Policy shall be administered by the Committee. Any determinations made by the Committee shall be final and binding on all affected individuals and their beneficiaries, heirs, executors, administrators, or other legal representatives. The Committee shall have full power and authority to (i) administer and interpret this Policy; (ii) correct any defect, supply any omission and reconcile any inconsistency in this Policy; and (iii) make any other determination and take any other action that the Committee deems necessary or desirable for the administration of this Policy and to comply with applicable law (including Section 10D of the Exchange Act) and applicable stock market or exchange rules and regulations. Notwithstanding anything to the contrary contained herein, to the extent permitted by Section 10D of the Exchange Act, the Board may, in its sole discretion, at any time and from time to time, administer this Policy in the same manner as the Committee.

3. **Definitions**. For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

(a) "***Accounting Restatement***" shall mean an accounting restatement (i) due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement).

(b) "***Board***" shall mean the Board of Directors of the Company.

(c) "***Clawback Eligible Incentive Compensation***" shall mean, in connection with an Accounting Restatement and with respect to each individual who served as an Executive Officer at any time during the applicable performance period for any Incentive-based Compensation (whether or not such individual is serving as an Executive Officer at the time the Erroneously Awarded Compensation is required to be repaid to the Company Group), all Incentive-based Compensation Received by such Executive (i) on or after the Effective Date, (ii) after beginning service as an Executive Officer, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the applicable Clawback Period.

(d) "***Clawback Period***" shall mean, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(e) "***Committee***" shall mean the Compensation Committee of the Board.

(f) "***Company***" shall mean Innoviva, Inc., a Delaware corporation.

(g) "***Company Group***" shall mean the Company, together with each of its direct and indirect subsidiaries.

(h) "***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

(i)"***Effective Date***" shall mean October 2, 2023.

(j)"***Erroneously Awarded Compensation***" shall mean, with respect to each Executive in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid.

(k)"***Executive***" shall mean any current or former Executive Officer.

(l)"***Executive Officer***" shall mean each individual who is designated as an "officer" of the Company in accordance with 17 C.F.R. 240.16a-1(f). Identification of an Executive Officer for purposes of this Policy would include at a minimum executive officers identified pursuant to 17 C.F.R. 229.401(b). The determination as to an individual's status as an Executive Officer shall be made by the Committee and such determination shall be final, conclusive and binding on such individual and all other interested persons.

(m)"***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and all other measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall for purposes of this Policy be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in the Company's financial statements or included in a filing with the SEC.

(n) "***Incentive-based Compensation***" shall mean any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(o)"***Nasdaq***" shall mean The Nasdaq Stock Market.

(p)"***Policy***" shall mean this Policy for the Recovery of Erroneously Awarded Compensation, as the same may be amended and/or restated from time to time.

(q)"***Received***" shall, with respect to any Incentive-based Compensation, mean actual or deemed receipt, and Incentive-based Compensation shall be deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if payment or grant of the Incentive-based Compensation occurs after the end of that period.

(r)"***Restatement Date***" shall mean the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

(s)"***SEC***" shall mean the U.S. Securities and Exchange Commission.

4.**Repayment of Erroneously Awarded Compensation**.

(a)In the event of an Accounting Restatement, the Committee shall promptly (and in all events within ninety (90) days after the Restatement Date) determine the amount of any Erroneously Awarded Compensation for each Executive in connection with such Accounting Restatement and shall promptly thereafter provide each Executive with a written notice containing the amount of Erroneously Awarded Compensation and a demand for repayment or return, as applicable. For Incentive-based Compensation based on (or derived from) stock price or total shareholder return where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder

return upon which the Incentive-based Compensation was Received (in which case, the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq).

(b) The Committee shall have broad discretion to determine the appropriate means of recovery of Erroneously Awarded Compensation based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. To the extent that the Committee determines that any method of recovery (other than repayment by the Executive in a lump sum in cash or property) is appropriate, the Company shall offer to enter into a repayment agreement (in a form reasonable acceptable to the Committee) with the Executive. If the Executive accepts such offer and signs the repayment agreement within thirty (30) days after such offer is extended, the Company shall countersign such repayment agreement. If the Executive fails to sign the repayment agreement within thirty (30) days after such offer is extended, the Executive will be required to repay the Erroneously Awarded Compensation in a lump sum in cash (or such property as the Committee agrees to accept with a value equal to such Erroneously Awarded Compensation) on or prior to the date that is one hundred twenty (120) days following the Restatement Date. For the avoidance of doubt, except as set forth in Section 4(d) below, in no event may the Company Group accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive's obligations hereunder.

(c) To the extent that an Executive fails to repay all Erroneously Awarded Compensation to the Company Group when due (as determined in accordance with Section 4(b) above), the Company shall, or shall cause one or more other members of the Company Group to, take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive. The applicable Executive shall be required to reimburse the Company Group for any and all expenses reasonably incurred (including legal fees) by the Company Group in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d) Notwithstanding anything herein to the contrary, the Company shall not be required to take the actions contemplated by Section 4(b) or 4(c) above if the following conditions are met and the Committee determines that recovery would be impracticable:

(i) The direct expenses paid to a third party to assist in enforcing the Policy against an Executive would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously Awarded Compensation, documented such attempts and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law where that law was adopted prior to November 28, 2022, provided that, before determining that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. **Reporting and Disclosure**. The Company shall file all disclosures with respect to this Policy in accordance with the requirement of the federal securities laws, including the disclosure required by the applicable SEC filings.

6. **Indemnification Prohibition**. No member of the Company Group shall be permitted to indemnify any Executive against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company Group's enforcement of its rights under this Policy. Further, no member of the Company Group shall enter into any agreement that exempts any Incentive-based Compensation from the application of this Policy or that waives the Company Group's right to recovery of any Erroneously Awarded Compensation and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

7.**Interpretation**. The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. Notwithstanding anything to the contrary herein, this Policy is intended to comply with the requirements of Section 10D of the Exchange Act (and any applicable regulations, administrative interpretations or stock market or exchange rules and regulations adopted in connection therewith). The provisions of this Policy shall be interpreted in a manner that satisfies such requirements and this Policy shall be operated accordingly. If any provision of this Policy would otherwise frustrate or conflict with this intent, the provision shall be interpreted and deemed amended so as to avoid such conflict. If any provision of this Policy is determined to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted by applicable law and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

8.**Effective Date**. This Policy shall be effective as of the Effective Date.

9. **Amendment**; **Termination**. The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed. The Committee may terminate this Policy at any time. Notwithstanding anything in this Section 9 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

10.**Other Recoupment Rights**; **No Additional Payments**. The Committee intends that this Policy will be applied to the fullest extent of the law. The Committee may require that any employment agreement, equity award agreement, or any other agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require an Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company Group under applicable law, regulation or rule or pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company Group. Any applicable award agreement or other document setting forth the terms and conditions of any compensation covered by this Policy shall be deemed to include the restrictions imposed herein and incorporate this Policy by reference and, in the event of any inconsistency, the terms of this Policy will govern. For the avoidance of doubt, this Policy applies to all compensation that is received on or after the Effective Date, regardless of the date on which the award agreement or other document setting forth the terms and conditions of the Executive's compensation became effective, including, without limitation, compensation received under the 2012 Equity Incentive Plan and any successor plan thereto.

11.**Successors**. This Policy shall be binding and enforceable against all Executives and their beneficiaries, heirs, executors, administrators, or other legal representatives.

* * *

This Policy was adopted by the Committee as of October 30, 2023.

Exhibit A

INNOVIVA, INC.
POLICY FOR THE
RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Innoviva, Inc. Policy for the Recovery of Erroneously Awarded Compensation (the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company Group. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company Group to the extent required by, and in a manner permitted by, the Policy.

_____
Signature

_____
Print Name

_____
Date